Utah Diabetes Practice Recommendations

Section 1 - 2004
Diabetes Management for Adults

Section 2 – April 2005
Diabetes in Pregnancy

Section 3 –May 2005
Diabetes Management for Inpatients

Diabetes Prevention & Control Program
UTAH DEPARTMENT OF HEALTH

www.health.utah.gov/diabetes

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Diabetes Management for Adults

This document was produced under Cooperative Agreement #U32/CCU8227012-02, Centers for Disease Control and Prevention. The contents of this document are solely the responsibility of the Utah DPCP and do not necessarily represent the official views of the Centers for Disease Control and Prevention

Endorsements

The following professional associations and groups have reviewed the sections of the Utah Diabetes Practice Recommendations that apply to their respective clinical areas of interest. They have endorsed these Recommendations, to the extent they apply to their clinical areas, and found them to be consistent with applicable standards of care for men and women with diabetes. In extending their endorsement, it is recognized that these recommendations, while outlining a general course of action for the majority of patients, do not substitute for informed clinical judgment on the exact course of treatment for individual patients.

Association of Diabetes Educators of Utah

Utah Academy of Family Practice

Utah Academy of Physician Assistants

Utah Chapter, American College of Physicians

Utah Department of Health

Utah Dietetic Association

Utah Diabetes Prevention and Control Program Advisory Board

Utah Nurses Association

Utah Nurse Practitioners

Utah Ophthalmology Society

Utah Optometric Association

Utah Pharmaceutical Association

Utah Podiatric Medical Association

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Special thanks to Betsi Briones for the charts and many revisions in these recommendations

UTAH DIABETES PRACTICE RECOMMENDATIONS 2004

Introduction

The Utah Diabetes Prevention and Control Program (DPCP) recognizes the importance of optimizing care for patients with diabetes. In promoting this objective, the DPCP organized a committee of interested health care professionals to develop the **Utah Diabetes Practice Recommendations - 2004** (UDPR). The recommendations are intended to foster current diabetes care practices, to provide useful outlines to guide healthcare professionals in screening and diagnosing people with diabetes, and to promote appropriate diabetes management. The materials in the UDPR build upon and complement national and regional diabetes protocols. Members of the UDPR Committee have identified decision points to assist the clinician in providing consistent and appropriate diabetes care for their patients.

Well designed and effectively carried out studies such as the **Diabetes Control and Complications Trial (DCCT)** and the **United Kingdom Prospective Diabetes Study (UKPDS)** have demonstrated convincingly that blood glucose control significantly affects the development of complications in individuals with either type 1 or type 2 diabetes. A direct link between blood glucose levels and the risk for complications has been firmly established, despite the fact that other factors such as genetics also play a significant role.

Providers should encourage individuals with diabetes to aim for the lowest blood glucose levels that do not place them at undue risk for hypoglycemia. The studies also show that any improvement in glucose control has the effect of slowing both the development and the progression of microvascular complications. Data from the UKPDS have shown the linear relationship between glycemic levels and the risk for complications. For each percentage point decrease in A1c, there was a 35% reduction in the risk for microvascular complications.

Clinical judgment is necessary to identify those patients for whom near normal glycemic control might not be appropriate. Near normalization of glycemic levels requires active participation by the patient and is not advisable for those who are neither capable nor willing to actively participate in their own diabetes management. It is not advised for very young children and may not be indicated for those whose impairments may compromise their ability to fully appreciate the regimens set forth in this document. There are some data that indicate that hypoglycemia in children could cause impaired brain development before the age of seven, while in older patients, hypoglycemia may lead to stroke or heart attack.

Acknowledgement

The DPCP acknowledges the fine work and efforts of the Diabetes Management Team and the Primary Care Clinical Program at Intermountain Health Care (IHC) in the development of the UDPR. Much of the material incorporated in the UDPR closely follows the Care Process Model outlined in the 2003 update of IHC's *Management of Adult Diabetes,* and is used with permission kindly provided by IHC.

Summary of Key Treatment Targets

Measure/Test	Target	Comment	Frequency
HbA1c	**<7.0%**	As low as possible without significant hypoglycemia	Test at least semi-annually
Blood Pressure	**<130/80 mm Hg**	<125/75 for patients with nephropathy	Check at each office visit
LDL Cholesterol	**<70-100 mg/dL (depending on presence of CVD)**	Data suggest treatment with statins may be appropriate for people age >40 with total cholesterol ≥135 mg/dL	Test at least annually
Urine Microalbumin or Microalbumin/ Creatinine Ratio	**<30 mg per 24 hours or <30 mg/g of creatinine**	Use one of the following: Micral (dipstick) Spot urine 24 hour urine Timed urine (<20 mcg/min)	Test at least annually
Dilated Eye Exam	**Normal**	High risk should be tested more frequently; low risk may require less often	Check annually
Foot Exam	**Identify Level of Risk**	Check every visit if significant vascular disease, poor protective sensation is present, or if identified as high risk	Complete an annual evaluation of pulses, test with monofilament fiber for loss of protective sensation, and question carefully about claudication

Guidelines for Frequency of Lab Tests and Examinations

Examination	Every 3 months for those who are not meeting blood glucose or blood pressure goals, on new therapy, on intensive insulin therapy, or with evidence of progression of microvascular or macrovascular disease Every 6 months for those who are meeting blood glucose and blood pressure goals, are not on new therapy, and do not have evidence of progression of microvascular or macrovascular disease
Hemoglobin A1c	Same as for examination above
Blood Glucose	If patient is self-monitoring blood glucose and records are acceptable: Optional If patient is not self-monitoring blood glucose: Test when fasting at each examination visit and correlate with A1c
Blood Pressure [1, 2]	Check and record at every visit
Foot Exams [3]	1. Screen feet annually: physical exam and sensory exam using a monofilament 2. Categorize findings: low or high risk Low risk: none of the 5 high risk characteristics listed below: High risk: one or more of the following: Loss of protective sensation Absent pedal pulses Severe foot deformity History of foot ulcer Prior amputation 3. High risk: screen at every visit
Dilated Eye Exam [4]	Annually for most patients with mild or no NDPR or microaneurisms, biennially for patients in good control with advise from an eye care professional
Microalbumin [5,6,7]	Annually
Fasting Lipid Profile	Annually
Influenza Vaccine	Annually
Pneumococcal Vaccine	Once before age 65. Consult physician about revaccination after 65
Self-Management Education	1. Upon diagnosis 2. When there are significant changes in therapy; the patient is not meeting targets; for pre-pregnancy counseling; and newly diagnosed gestational diabetes 3. Annually reassess need for education
Refer to Specialists	1. As needed, when not meeting targets 2. As needed, when complications are noted
Dental Exam	At least annually for preventive care

1. If BP is 130-139/80-89 initiate exercise and nutritional intervention, if not effective use ACE-I, ARB or Thiazide diuretic; if BP >140/90 initiate lifestyle modification + ACE-I, ARB or diuretic; if >150/90, consider initial two drug therapy with ACE-I or ARB + Thiazide diuretic
2. Unless contraindicated, use low dose aspirin as a prophylactic measure at onset of vascular risk and/or after age 40: (Low dose: 81 mg to 325 mg every day)
3. Refer to "Feet Can Last a Lifetime" packet for additional foot screening information (www.ndep.nih.gov).
4. Exception: Examine when planning pregnancy if possible and in first trimester with close follow-up
5. Screen for protein before testing for microalbumin. If protein is present, it is not necessary to perform any tests for microalbumin.
6. Consider using ACE inhibitors if microalbumin levels are >30mg/24 hours as determined by a 24 hour urine collection or spot urine microalbumin/creatinine ratio >30 (on at lease two separate occasions).
7. Exception: Screen in first trimester in pregnancy.

Diabetes in Utah and the United States

Prevalence

Diabetes has received considerable attention in the health care community and the news media in recent years due to the rapid increase in prevalence rate. It represents a growing public health and clinical concern in Utah and the United States (U.S.). The most recent estimate for diabetes prevalence in the U.S. shows 18.2 million people have diabetes. Unfortunately, over 5 million of those with diabetes are unaware they have the disease. The Utah Health Status Survey indicates that there were 120,000 Utahns with diabetes in 2001, a 48% increase over the 81,000 in the same survey in 1991. Of those Utahns with diabetes, an estimated 40,000 are untreated because they have not been diagnosed.

Complications

Diabetes is responsible for or associated with a number of serious and potentially fatal complications. It is estimated that up to **75% of individuals with diabetes die prematurely from heart disease.** Diabetes increases the risk of **heart attack and stroke** two to four fold; it is responsible for about half of all new cases of **kidney dialysis,** and is the leading **cause of blindness** among working age adults. Over half of all non-traumatic **lower extremity amputations** are related to complications of diabetes.

Costs

Diabetes is a common and potentially disabling, chronic disease that costs this country over $132 billion a year. Studies indicate that Medicare costs for people with diabetes are double the costs for those without diabetes. In the Medicaid population and among the uninsured, the cost ratios are 4:1. In most other groups costs are triple those of people without the disease.

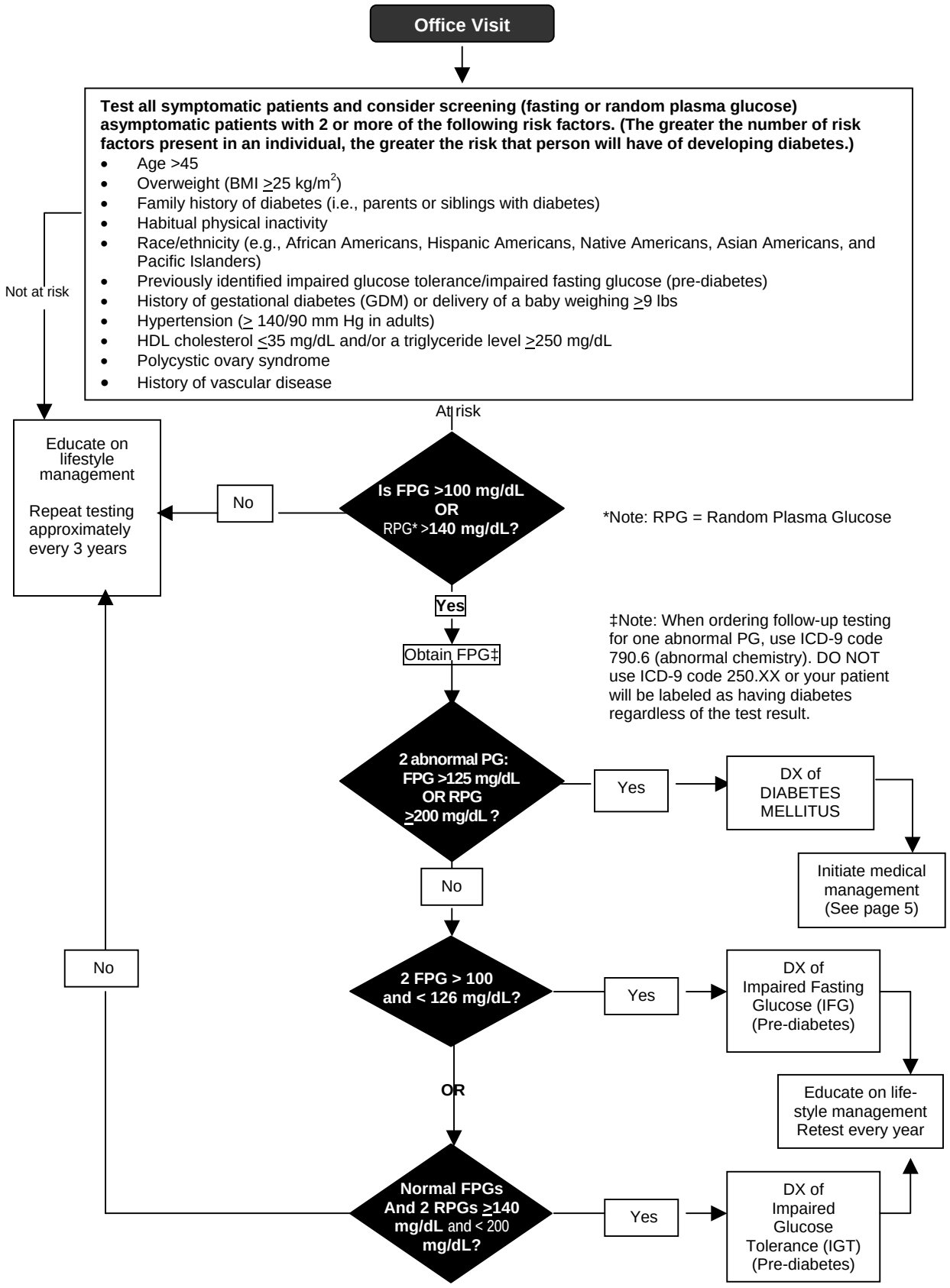
Pre-diabetes and metabolic syndrome

Diabetic risk factors of *impaired glucose tolerance* (IGT) and *impaired fasting glucose* (IFG) have come to be known as pre-diabetes. The American Diabetes Association estimates that 22 million people in the U.S. have this condition that puts them at high risk for diabetes. Many people with pre-diabetes also fit into a category known as *metabolic syndrome*. A patient can be considered to have *metabolic syndrome* if he or she has any 3 of the following 5 criteria established by the third Adult Treatment Panel (ATP III) of the National Cholesterol Education Program as indicated below:

- Increased waist circumference (>40 inches in men; >35 inches in women)
- Plasma triglycerides $\geq$150 mg/dL
- Plasma high-density lipoprotein (HDL) cholesterol <40 mg/dL (men) or <50 mg/dL (women)
- Blood pressure $\geq$130/85 mm Hg
- Fasting plasma glucose $\geq$100 mg/dL

Patients with either metabolic syndrome or pre-diabetes should be regularly screened for diabetes mellitus.

DIABETES SCREENING PROTOCOL

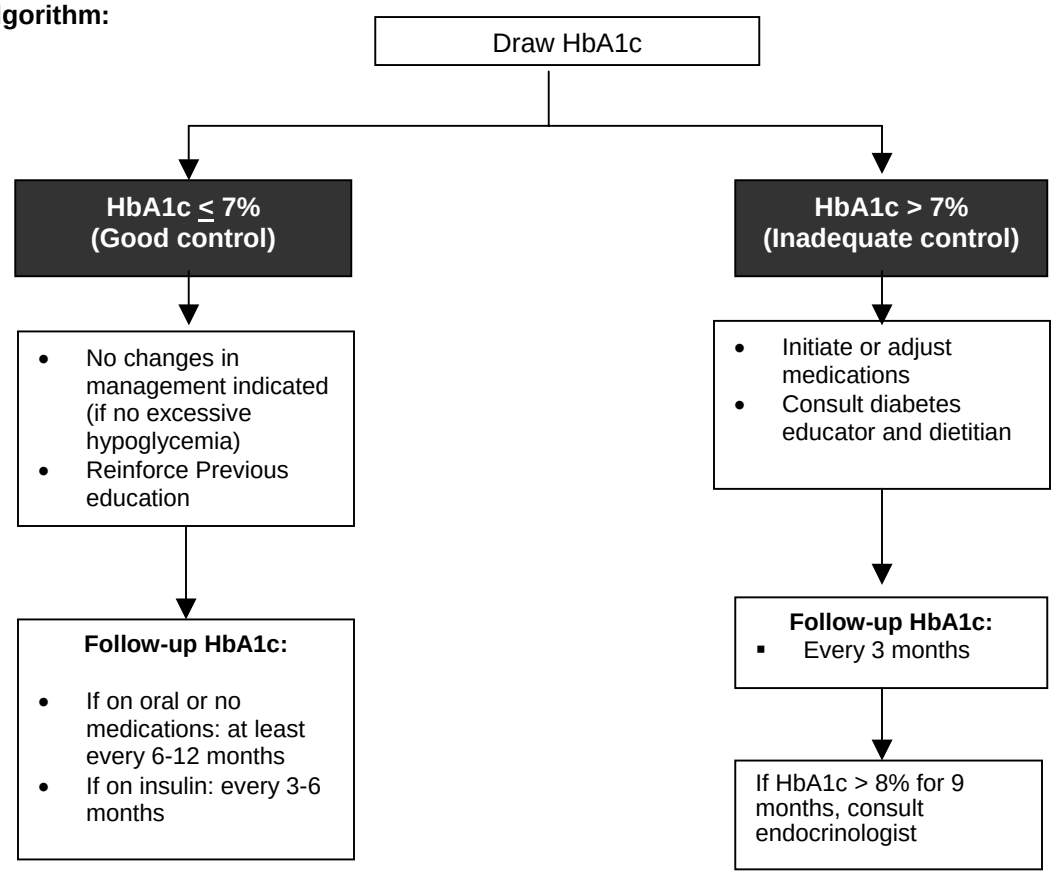


THE ROLE OF HbA1c IN DIABETES MANAGEMENT

HbA1c testing is *not* recommended as an initial screening test for diabetes mellitus, nor does it dictate day-to-day management of diabetes. Rather, it is an indication of the overall trend of blood glucose levels for the previous three months. Monitoring of glycemic status is considered a cornerstone of diabetes care and affects how physicians and patients adjust medical therapy as well as behavioral therapy (e.g. diet and exercise). The better the diabetes control, the lower the HbA1c, and the fewer the complications. The HbA1c value can also be used to validate (or call into question) the patient's home record of blood glucose readings and/or random FPG testing performed in the office.

GOAL: HbA1c below 7% or as low as possible without significant hypoglycemia.

Algorithm:



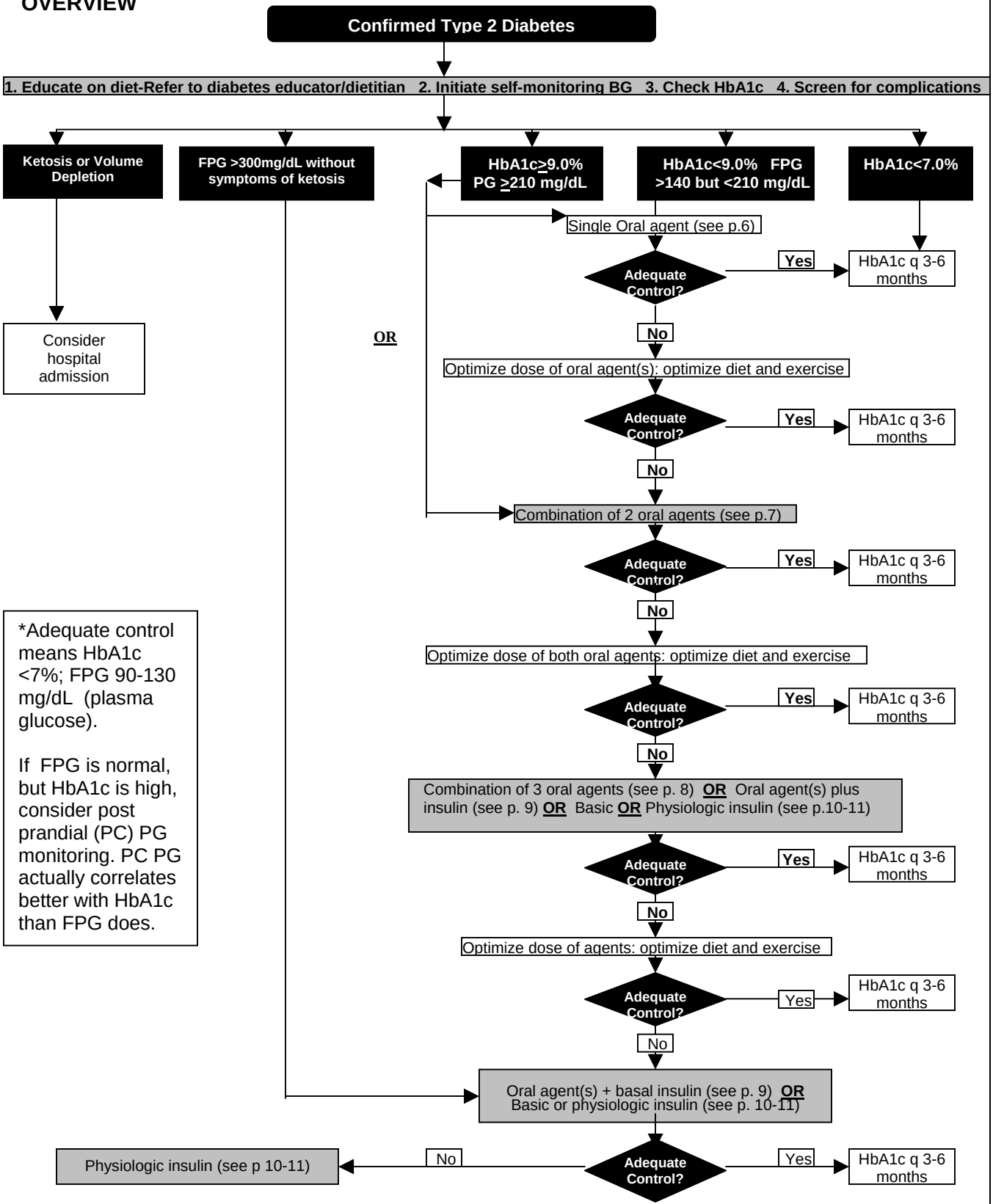
Note: Occasionally HbA1c values do not accurately reflect glycemic control. If serum glucose levels are higher than would be predicted by an HbA1c, consider measuring serum fructosamine.

The table to the right provides an approximate comparison of *average* plasma glucose (PG) and HbA1c values

Plasma Glucose	HbA1c %
345	12
310	11
275	10
240	9
205	8
170	7
135	6

MEDICAL MANAGEMENT

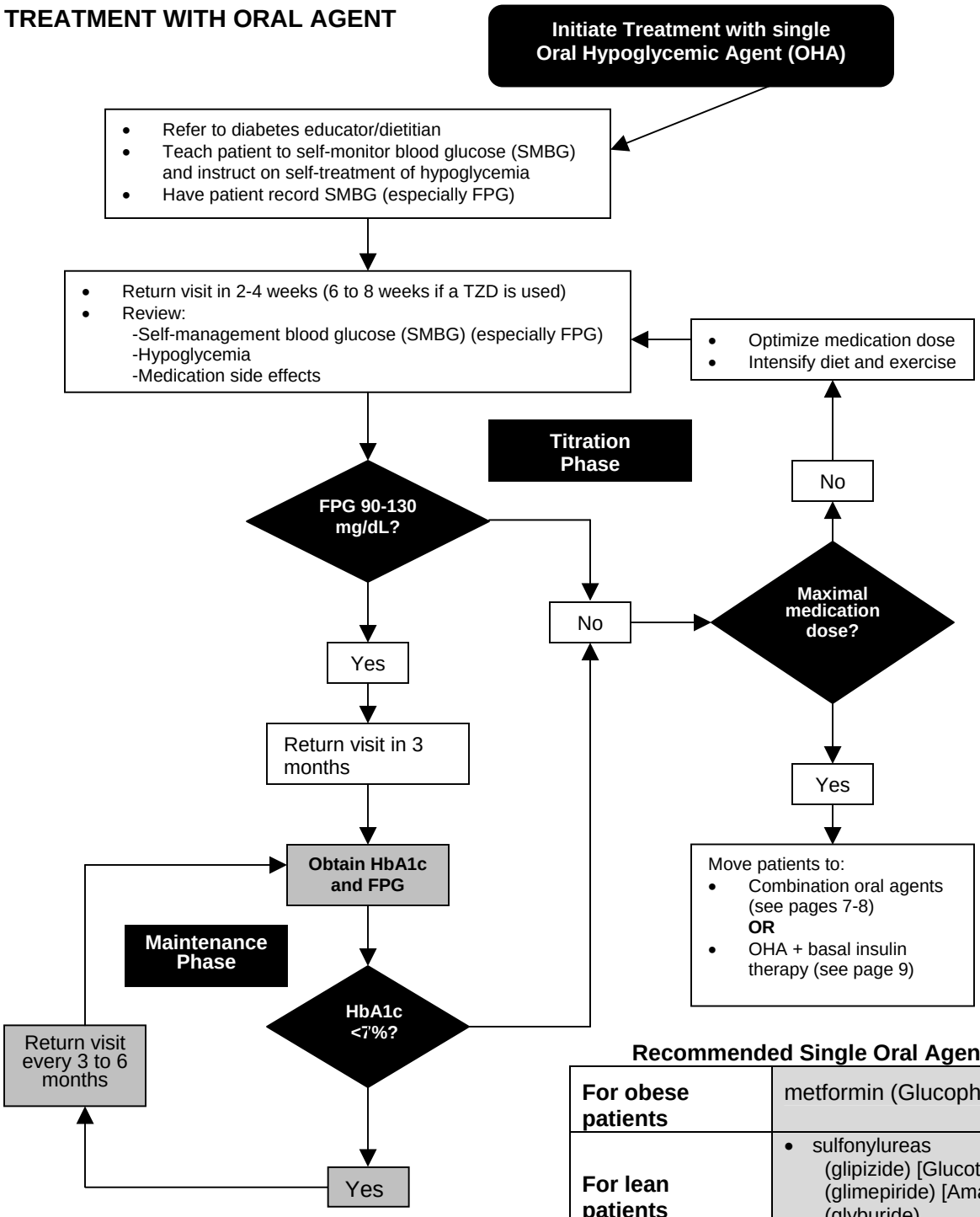
OVERVIEW



*Adequate control means HbA1c <7%; FPG 90-130 mg/dL (plasma glucose).

If FPG is normal, but HbA1c is high, consider post prandial (PC) PG monitoring. PC PG actually correlates better with HbA1c than FPG does.

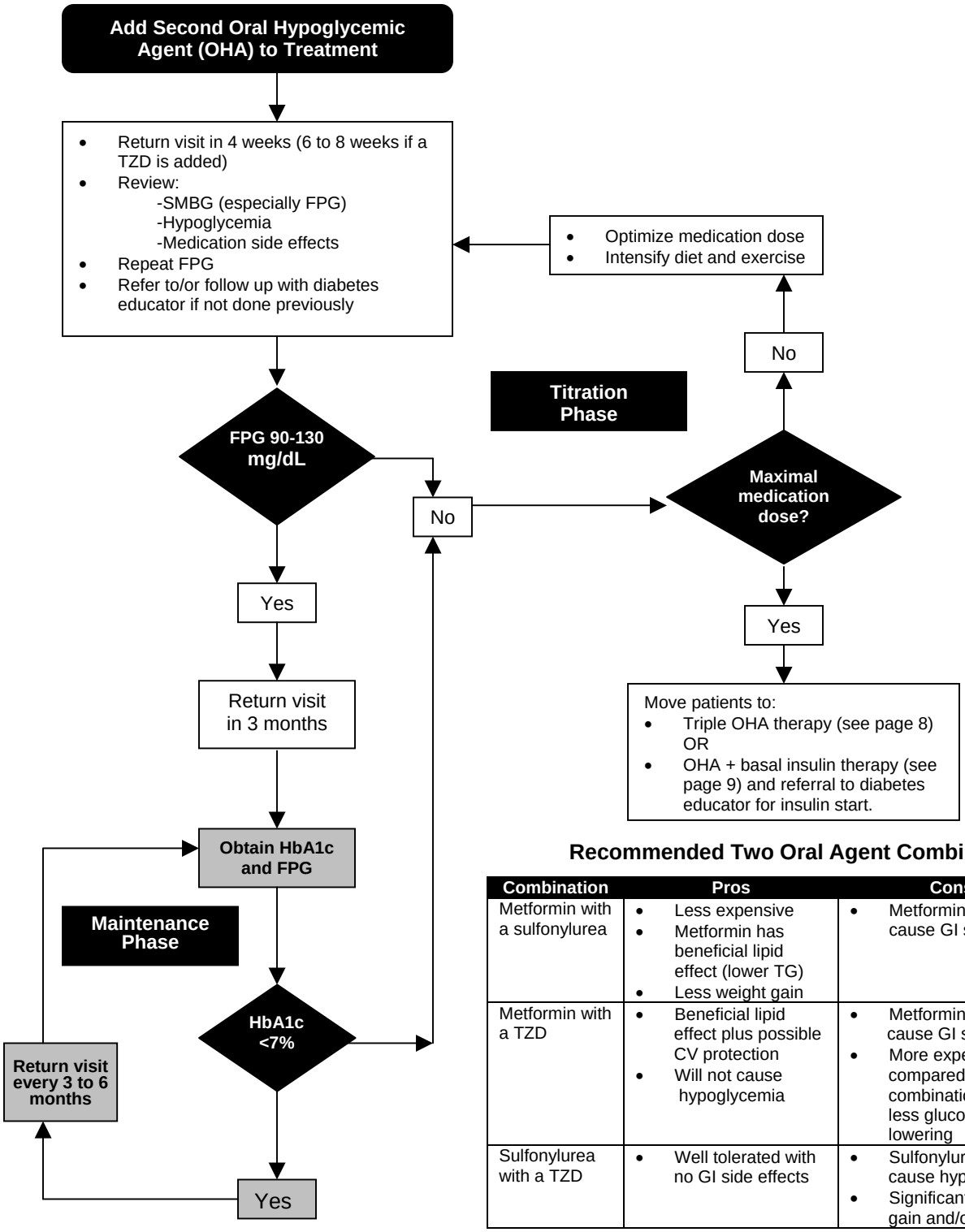
TREATMENT WITH ORAL AGENT



Recommended Single Oral Agents

For obese patients	metformin (Glucophage)
For lean patients	• sulfonylureas (glipizide) [Glucotrol] (glimepiride) [Amaryl] (glyburide) OR • metformin
Other Choices	• rosiglitazone (Avandia) • pioglitazone (Actos)

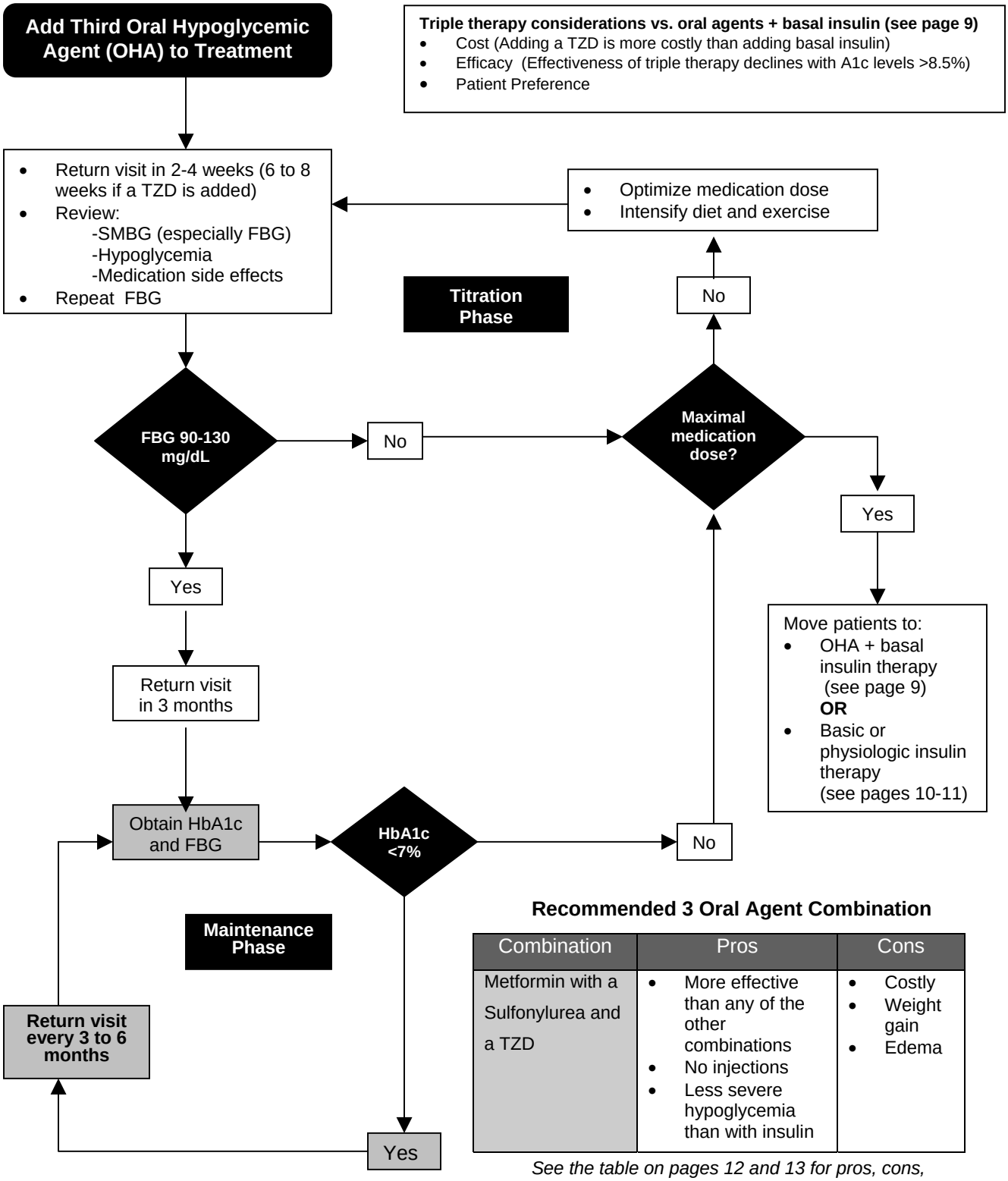
TREATMENT WITH TWO ORAL AGENTS



Recommended Two Oral Agent Combinations

Combination	Pros	Cons
Metformin with a sulfonylurea	• Less expensive • Metformin has beneficial lipid effect (lower TG) • Less weight gain	• Metformin may cause GI side effects
Metformin with a TZD	• Beneficial lipid effect plus possible CV protection • Will not cause hypoglycemia	• Metformin may cause GI side effects • More expensive compared to other combinations, with less glucose lowering
Sulfonylurea with a TZD	• Well tolerated with no GI side effects	• Sulfonylureas may cause hypoglycemia • Significant weight gain and/or edema

TREATMENT WITH THREE ORAL AGENTS

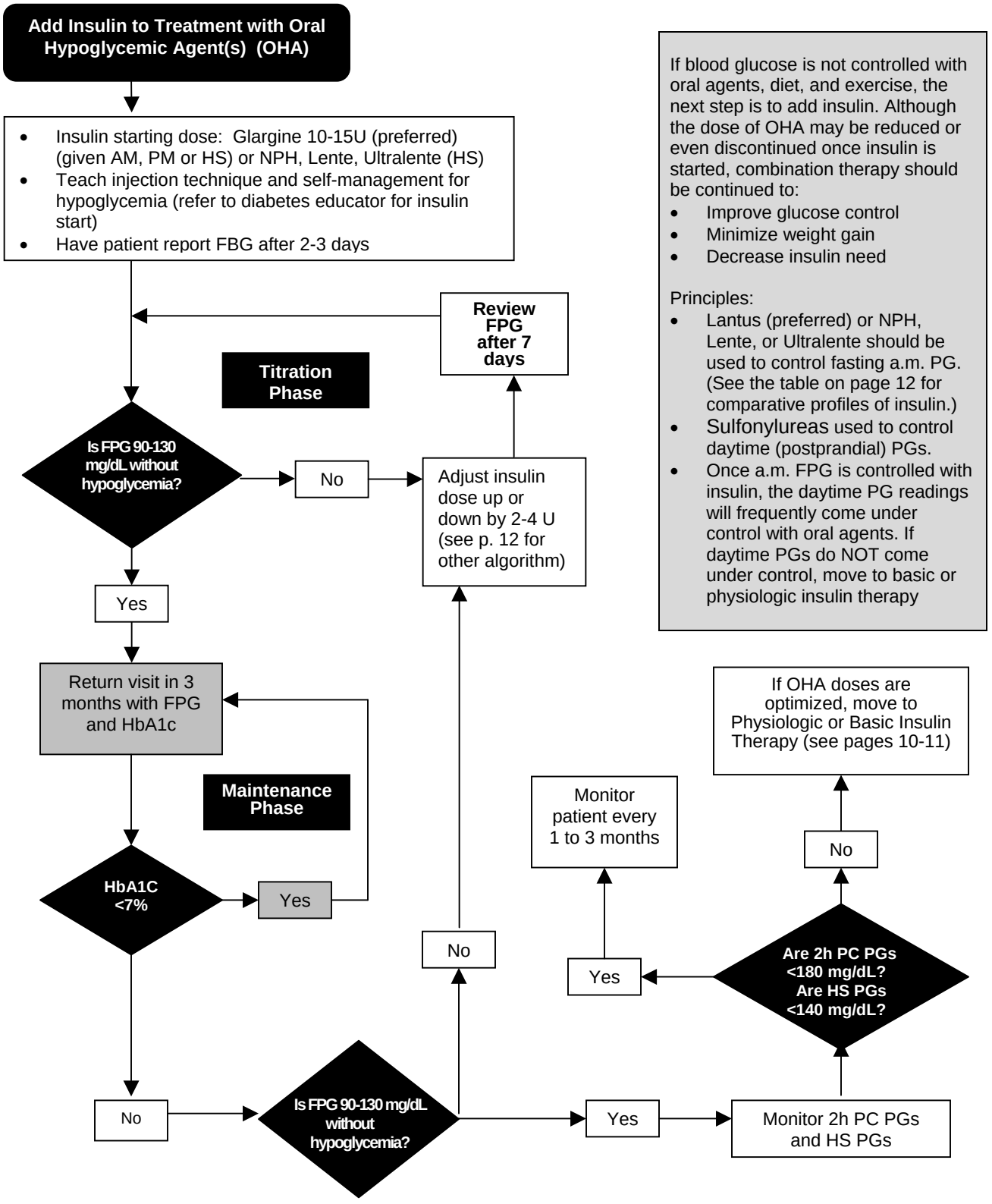


Recommended 3 Oral Agent Combination

Combination	Pros	Cons
Metformin with a Sulfonylurea and a TZD	• More effective than any of the other combinations • No injections • Less severe hypoglycemia than with insulin	• Costly • Weight gain • Edema

See the table on pages 12 and 13 for pros, cons, dosing and cost for oral agents

TREATMENT WITH ORAL AGENT(S) PLUS INSULIN



If blood glucose is not controlled with oral agents, diet, and exercise, the next step is to add insulin. Although the dose of OHA may be reduced or even discontinued once insulin is started, combination therapy should be continued to:

- Improve glucose control
- Minimize weight gain
- Decrease insulin need

Principles:

- Lantus (preferred) or NPH, Lente, or Ultralente should be used to control fasting a.m. PG. (See the table on page 12 for comparative profiles of insulin.)
- Sulfonylureas used to control daytime (postprandial) PGs.
- Once a.m. FPG is controlled with insulin, the daytime PG readings will frequently come under control with oral agents. If daytime PGs do NOT come under control, move to basic or physiologic insulin therapy

INSULIN THERAPY

Principles

- Basic insulin regimens are NOT designed to mimic normal insulin physiology.
- Basic insulin regimens are NOT recommended for type 1 patients.
- Basic insulin regimens are sometimes adequate for control of type 2 patients who have failed maximum efforts with oral medications or oral medications plus insulin.
- Basic insulin regimens are sometimes chosen when patients are not able to involve themselves in a physiologic multiple daily dose regimen.
- Consistency with meals and adequate adherence to a medical nutrition therapy plan are important to success of basic insulin regimens.
- Patients on basic insulin therapy regimens should move to physiologic (basal/bolus) insulin if goals are not met with basic insulin therapy.

Sample Basic Insulin Regimens

The following are some basic insulin regimens. See the table on page 12 for comparative profiles of insulin.

Pre-mixed Insulins

All of the following are BID (pre-breakfast and pre-supper)

- 70/30 (NPH Regular)
- 70/30 (NPA NovoLog)
- 75/25 (NPL Humalog)

Split-mixed Insulins

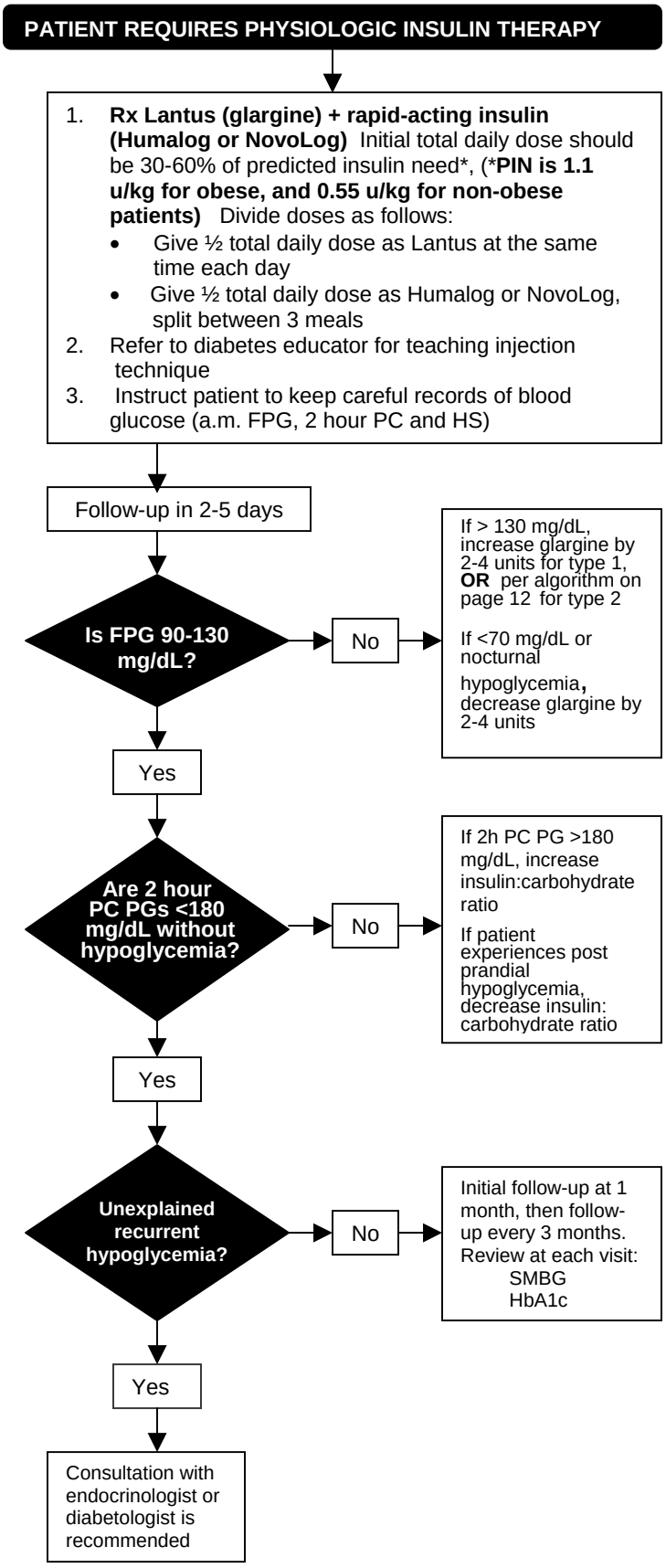
- NPH or Lente BID (either a.m. and supper, or a.m. and HS) with:
  - Regular insulin before breakfast and before supper
    OR
  - Humalog or NovoLog before breakfast and before supper

PHYSIOLOGIC (BASAL/BOLUS) INSULIN

Principles

- This more intensive insulin regimen provides closest approximation to normal insulin physiology. It uses Lantus insulin for basal metabolic control, and Humalog or NovoLog for prandial control and correction of high glucose levels.
  - Lantus is used to control glycemia in the basal state when not eating. The period from bedtime until breakfast is the best reflection of this. Bedtime snacking is NOT recommended.
  - Rapid-acting insulin (Humalog or NovoLog) is added prior to each meal (See the algorithm on the following page for recommended initial dosing). This insulin is adjusted to prevent postprandial hyperglycemia or hypoglycemia. Late postprandial blood sugar (4 hours after a meal) should be equal to pre-meal blood sugar.
  - Pre-meal Humalog or NovoLog doses are usually determined by carbohydrate counting and use of a carbohydrate ratio. A less commonly used strategy is pre-meal insulin based on a fixed meal plan. **In either case, training in medical nutrition therapy by a qualified dietitian, and training in insulin use by a qualified diabetes educator, are recommended for success.**
- Almost all type 1 patients should be on basal/bolus regimens. Most type 2 patients requiring insulin will benefit from basal/bolus insulin to attain good control.
- Instruction for modifying insulin doses for exercise and sick days should be incorporated into the regimen.

INITIAL PHYSIOLOGIC INSULIN REGIMEN



Using the 1700 Rule

The 1700 rule can be used to guide the patient's dosage of insulin in two circumstances:

- To calculate a sliding scale to determine a correction dose for a high PG reading
- To calculate insulin-to-carbohydrate ratio (i.e., to anticipate insulin needed to cover the carbohydrate content of a meal)

To calculate a sliding scale:

1. **Determine the current total daily dose (TDD):** Add up ALL the insulin the patient takes in a 24 hour period (short + long-acting).
2. **Divide 1700 by the TDD.** This is the predicted amount (mg/dL) the PG will lower for every 1 unit of Humalog or NovoLog insulin added.
3. **Increase Humalog or NovoLog** by the number of units needed to reduce the PG to an appropriate level (<140 mg/dL)).
4. **Encourage the patient to keep careful records** of resulting PG readings. (Most helpful readings are a.m. FPG, 2-3 hours PC, and HS).

   Example
   1. Patient takes 50 units of insulin/day **(TDD = 50**)
   2. **1700/50 = 34** (Round to a convenient number like 35, which means 1 unit of insulin will lower PG by ~35 points)
   3. So, if PG is 175, use 1 extra unit to drop it to 140. If PG is 210, use 2 extra units, etc.

To calculate insulin-to-carb ratio:

1. **Determine the current total daily dose (TDD):** Add up ALL the insulin the patient takes in a 24-hour period (short + long-acting)
2. **Divide 1700 by the TDD.** This is the predicted amount (mg/dL) the BG will lower for every 1 unit of Humalog or NovoLog insulin added.
3. **Multiply predicted PG lowering (mg/dL) x .33** This is the number of grams of carbohydrate covered by 1 unit of insulin. (For most people, a starting dose would be 1 unit of Humalog or NovoLog insulin for every 10-15 grams of carbohydrate to be eaten.)

   Example
   1. Patient takes 50 units of insulin/day **(TDD = 50)**
   2. **1700/50 = 34** (round to 35, which means 1 unit of insulin lowers BG by ~35 points)
   3. **35 X .33 = 11-12** (which means patient will need 1 unit of insulin for every 11-12 grams of carbohydrate anticipated in a meal)

INSULIN & ORAL MEDICATIONS

GLARGINE (Lantus) or NPH TITRATION ALGORITHM (as basal insulin)

Start with 10-15 units/day and adjust weekly

Mean of FPG values from preceding 2 days	Increase insulin dose/day
>180 mg/Dl	8 units
140-180 mg/dL	6 units
120-139 mg/dL	4 units
100-119 mg/dL	2 units

Riddle MC et al: *Diabetes Care* (2003) 26: 3080-86

COMPARATIVE PROFILES OF INSULIN

Insulin	Description	Onset	Peak	Usual Effective Duration	Usual Maximum Duration	January 2004 AWP
Humalog/NovoLog	Clear	15 min	1-1½ hrs	1-3 hrs	3-4 hrs	10 ml: $67
Regular	Clear	30-60 min	2-3 hrs	3-6 hrs	4-8 hrs	10 ml: $31
NPH	Cloudy	2-4 hrs	4-10 hrs	10-16 hrs	14-18 hrs	10 ml: $31
Lente	Cloudy	3-4 hrs	4-12 hrs	12-18 hrs	16-20 hrs	10 ml: $31
Ultralente	Cloudy	6-10 hrs	unknown	18-20 hrs	20-30 hrs	10 ml: $31
Glargine (Lantus)*	Clear	1 hr	none	24 hrs	24 hrs	10 ml: $51

* Notes about Lantus:

- Lantus is preferred over other long-acting insulin because of better control of a.m. fasting PG with decreased hypoglycemia, especially nocturnally. Must be given at same time each day.
- Due to improved stability of PG control, Lantus appears to be the optimum insulin for combination with oral agents or as basal insulin in physiologic insulin therapy.
- Administer Lantus once daily for individuals with type 1 and type 2 who require basal (long-acting) insulin for control of hyperglycemia—in a.m. with oral agents, and at supper or HS in physiologic insulin therapy in combination with short-acting insulin.
- Lantus cannot be diluted or mixed with other types of insulin or solutions.
- Administer Lantus subcutaneously ONLY—not to be given IV.

ORAL AGENT MEDICATION SUMMARY

	Generic Name	Brand Name	Dosing	30 Day AWP January 2004	Pros	Cons
Metformin	metformin	Glucophage	500 mg BID (start) to 1000 mg BID	**Generic:** 500 mg BID $42 850 mg BID $72 1000 mg BID $87	▪ Prevents weight gain (preferred for obese patients-most type 2 diabetics) ▪ Favorable lipid effects ▪ No hypoglycemia ▪ Maximum PG effect at 3-4 weeks ▪ Decreases formation of advanced glycosylation end products (AGE) ▪ Most benefit derived at 1500-1700 mg/day	▪ GI distress (nausea and/or diarrhea) ▪ CAUTION - increased risk of acidosis: **- STOP MED with acute illness, dehydration, or IV contrast dyes** ▪ DO NOT use for patients with chronic liver disease, CHF, renal failure (e.g., creatinine ≥1.5 men or ≥ 1.4 women), alcoholism, or decreased creatinine clearance in elderly
	metformin XR	Glucophage XR	500-1500 mg @ supper	**Generic:** 500 mg QD $23 1500 mg QD $67 2000 mg QD $89		
Sulfonylureas	glipizide XL	Glucotrol XL	5 mg QD to 20 mg QD (max) [may give dose BID]	**Generic:** 5 mg QD $13 10 mg QD $25	▪ Preferred for lean patients (small % of type 2) ▪ Well tolerated ▪ Can be combined with oral agents except Prandin, Starlix, or other sulfonylureas ▪ Maximum PG effect at 5-7 days ▪ Most benefit derived at 50% of maximum dose	▪ Higher risk for hypoglycemia and weight gain ▪ Do not use with Prandin or Starlix, or other sulfonylureas
	glimepiride	Amaryl	1 mg QD to 8 mg QD (max)	**Brand Only:** 1 mg QD $12 2 mg QD $19 4 mg QD $37		

ORAL AGENT MEDICATION SUMMARY (continued)

	Generic Name	Brand Name	Dosing	30 Day AWP January 2004	Pros	Cons
Combination	metformin + glipizide	Metaglip	2.5 mg/500 mg QD to BID 5 mg/500 mg QD to BID	**Brand Only:** 2.5 mg/500 mg BID $64 5 mg/500 mg BID $64	▪ Less expensive ▪ Metformin has beneficial lipid effects (lower triglycerides) ▪ Less weight gain	▪ Metformin may cause GI side effects ▪ Do not use with Prandin or Starlix
	metformin + glyburide	Glucovance	1.25 mg/250 mg BID w/meals 5 mg/500 mg BID to TID w/meals	**Brand Only:** 1.25 mg/250 mg BID $59 5 mg/500 mg BID $69		
	metformin + Avandia (rosiglitazone)	Avandamet	2 mg/500 mg 1-2 BID 4 mg/500 mg 1-2 BID	**Brand Only:** 2 mg/500 mg 1 BID $106 4 mg/500 mg 1 BID $172	▪ Beneficial lipid effects plus possible CV protection ▪ Does not cause hypoglycemia	▪ Metformin may cause GI side effects ▪ More expensive when compared to other combinations, with less glucose lowering
TZDs	pioglitazone	Actos	15-45 mg QD (increasing dose slowly may decrease edema)	**Brand Only:** 15 mg QD $109 30 mg QD $175 45 mg QD $189	▪ Good option for patients who are intolerant of metformin ▪ Does not cause hypoglycemia ▪ Lowers serum insulin ▪ Favorable lipid effects (best with Actos); may help further decrease TG levels ▪ Appears to have prolonged benefits with lower secondary failure rate ▪ Improves many CV risk factors and may be cardiovascular protective	▪ Edema can be significant, especially if given with insulin ▪ Fluid retention may lead to or exacerbate heart failure (**in this circumstance, drug should be stopped)** ▪ Consider checking LFTs q 2 mos x 1 yr; but appears risks are low or absent ▪ Expensive ▪ Actos may change metabolism of birth control pills ▪ Slow onset; maximum effect takes 6-12 weeks
	rosiglitazone	Avandia	2-8 mg QD (increasing dose slowly may decrease edema)	**Brand Only:** 2 mg QD $64 4 mg QD $91 8 mg QD $168		
Miglitinides	repaglinide	Prandin	0.5 mg PC with each meal 16 mg/day (max)	**Brand Only**: 0.5mg TID $99 1mg TID $99 2mg TID $99	▪ Short-acting; increases insulin release PC ▪ Lower risk of hypoglycemia than sulfonylureas (similar mechanism of action)	▪ Frequent dosing ▪ Increased cost ▪ Do not use with sulfonylureas ▪ Does not control FBG as well as sulfonylureas
	nateglinide	Starlix	120 mg PC TID (start and maintenance) 60 mg PP TID if HbA1c is close to goal	**Brand only:** 120 mg TID $112 60 mg TID $108	▪ Improves first-phase insulin release ▪ Can be used as monotherapy or in combination with other oral agents (except sulfonylureas) ▪ May lower risk of hypoglycemia	▪ Frequent dosing ▪ Increased cost ▪ Do not use with sulfonylureas ▪ Does not control FBG as well as well as sulfonylureas
A lpha Glucosdiase Inhibitors	acarbose	Precose	25 mg TID (start) to 100 mg TID (max)	**Brand Only:** 25 mg TID $65 50 mg TID $70 100 mg TID $83	▪ Does not cause hypoglycemia ▪ Not a systemic agent ▪ Inhibits/delays digestion of ingested carbohydrates	▪ Increased cost ▪ GI side effects common ▪ Frequent dosing ▪ Modest impact on HbA1c
	miglitol	Glyset	50-100 mg TID with meals	**Brand Only:** 50 mg TID $74 100 mg TID $87		

MANAGEMENT OF DIABETES RELATED CONDITIONS

CARDIOVASCULAR DISEASE

Patients with diabetes have 2- to 4-fold increased risk of coronary heart disease (CHD). The risk for CHD is increased much more dramatically in women with diabetes. All individuals with diabetes have a higher fatality rate once they have CHD than those without diabetes.

Multifactorial Intervention to Reduce Risk

Interventions that are well established

Research has established that modification of certain risk factors commonly associated with diabetes can substantially reduce the risk of cardiovascular disease. Well established interventions are listed below. Persons with diabetes benefit from these interventions to an extent that exceeds that seen in non-diabetic patients.

- Antiplatelet therapy
- Smoking cessation
- LDL cholesterol lowering
- Control of blood pressure

Interventions with supporting risk reduction data

Other issues with some data supporting a role in reduction of cardiovascular risk including the following:

- Administration of ACE inhibitors (MICRO-HOPE study)
- Treatment of diabetic dyslipidemia (This term refers to elevated triglyceride and low HDL cholesterol. Most often these two conditions are seen together, but some patients will have isolated low HDL cholesterol. These lipid abnormalities have been identified as secondary targets of therapy in diabetes after correction of LDL cholesterol elevations.)

Emerging risk factors

Emerging risk factors are those factors for which there appears to be substantial association with cardiovascular risk, but for which evidence is currently lacking to show that modification reduces risk. Consensus of opinion on how to handle these emerging risk factors (listed below) is still evolving.

- High sensitivity C-reactive protein (hsCRP)
- Homocysteine levels

CV Screening

Patients with symptoms suggesting CHD should undergo evaluation using exercise stress testing, myocardial perfusion imaging, stress echocardiography, or coronary angiography.

The value of screening of the asymptomatic individual for CHD is still of some uncertainty. While CHD is much more prevalent among those with diabetes, there is little evidence that screening procedures in asymptomatic persons has a positive effect on outcomes. As of yet, there is no consensus of opinion on which diagnostic test is the best choice for evaluating the asymptomatic patient. Nevertheless, consider screening by exercise stress test (with or without perfusion imaging) based on accumulated risk factors, the presence of other vascular disease, or abnormalities on a resting EKG.

CARDIOVASCULAR DISEASE (continued)

CV Medication Recommendations

Beta blockers

Patients with known coronary artery disease (CAD), especially if they have had a coronary event, may benefit from beta blockers.

Aspirin Therapy

- *Secondary prevention:* Use aspirin therapy as a *secondary* prevention strategy in men and women with diabetes who already have evidence of large-vessel disease. This includes diabetic individuals with a history of myocardial infarction, vascular bypass procedure, stroke or transient ischemic attack, peripheral vascular disease, claudication, and/or angina
- *Primary prevention:* Use aspirin therapy as a *primary* prevention strategy for high-risk men and women who have type 1or type 2 diabetes. This includes individuals with diabetes who have one or more of the following:
    - Family history of CHD
    - Cigarette smoking
    - Hypertension
    - Overweight (Body Mass Index [BMI] ≥25)
    - Albuminuria (micro or macro)
    - Hyperlipidemia:
        - Tchol >200 mg/dL
        - LDL >100 mg/dL
        - HDL <45 mg/dL for men
HDL <55 mg/dL for women
        - TG >150 mg/dL
    - Age >40 yrs
- *Individuals who may NOT be candidates for aspirin therapy:*
    - Individuals with diabetes under the age of 40 without CV risk factors listed above
    - People with aspirin allergy, bleeding tendency, anticoagulation therapy, recent gastrointestinal bleeding, and clinically active hepatic disease

ASPIRIN DOSAGE RECOMMENDATION:
Enteric-coated aspirin in doses of 81-325 mg/day

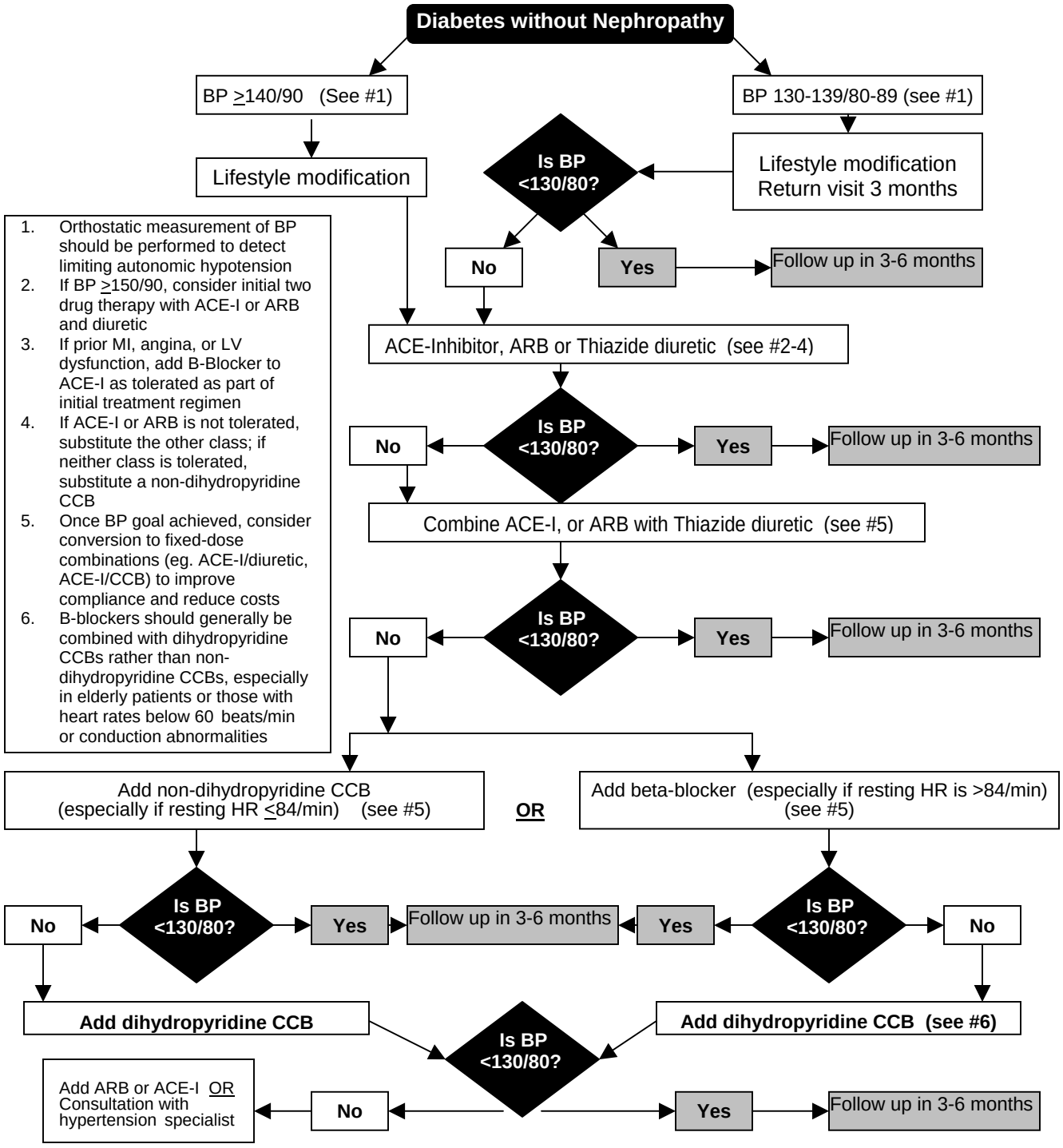
BLOOD PRESSURE CONTROL WITHOUT NEPHROPATHY

Aggressive treatment of high blood pressure in people with diabetes can reduce their cardiovascular risk. Lowering blood pressure to <130/80 mm Hg has a beneficial effect in reducing diabetic complications that is at least equal to the effect of glucose control. Microvascular complications of diabetes have also been shown to occur less frequently with lower blood pressure

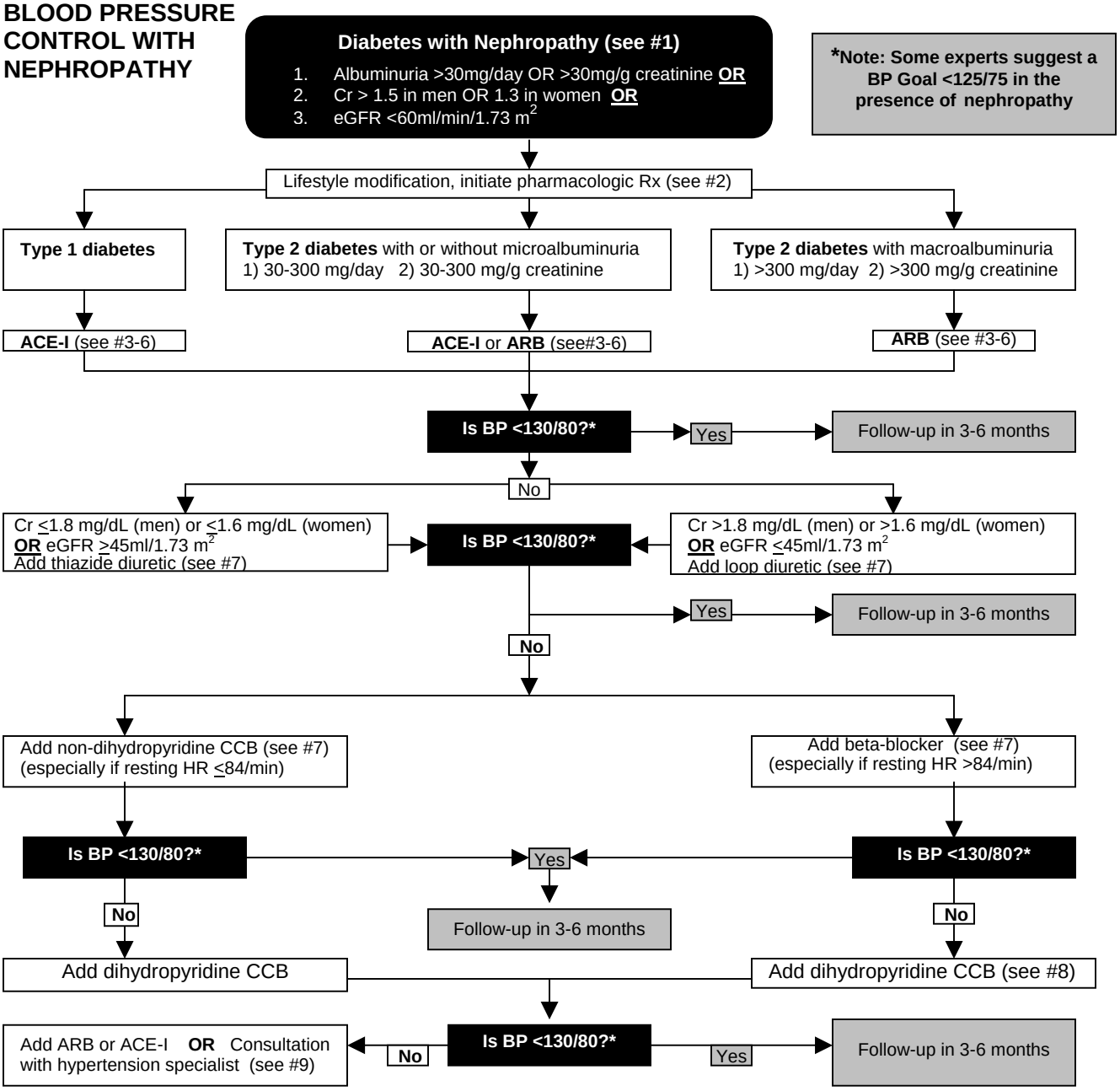
Goals: (CHECK AT EACH OFFICE VISIT)

- **<130/80 mm Hg for patients without nephropathy**
- **Some experts would lower the BP goal to <125/75 in the presence of nephropathy (see page 17)**

Note: The majority of patients require more than one medication to control blood pressure to these levels**.**



BLOOD PRESSURE CONTROL WITH NEPHROPATHY



1. Orthostatic measurement of BP should be performed to detect limiting automonic neuropathy with orthostatic hypotension
2. The finding of albuminuria in type 1 or 2 diabetic patients is an indication for treatment with an ACE-I or ARB irrespective of BP levels
3. If BP ≥150/90, consider initial two drug therapy with ACE-I or ARB and diuretic
4. If prior MI, angina, or LV dysfunction, add beta-blocker to ACE-I as tolerated as part of initial treatment
5. If ACE-I or ARB is not tolerated, substitute the other class; if neither class is tolerated, substitute a non-dihydropyridine CCB
6. Renal function and serum potassium must be closely monitored in patients with renal insufficiency. ACE-I and ARBs are relatively contraindicated in patients with Cr≥3.0 or eGFR <20 ml/min. If renal function deteriorates significantly (>25-35%), with ACE-I or ARB, consider work-up for renal artery disease
7. Once BP goal is achieved, consider conversion to fixed-dose combinations (e.g. ACE-I/diuretic, ACE-I/CCB) to improve compliance and reduce costs
8. Beta-blockers should generally be combined with dihydropyridine CCBs rather than non-dihydropyridine CCBs, especially in elderly patients or those with heart rates below 60 beats/min or conduction abnormalities. Combination therapy can cause severe bradycardia and cardiac syncope
9. Combining ACE-I and ARB may lower BP and reduce proteinuria; long-term studies are not available

HYPERTENSION MEDICATION RECOMMENDATIONS

Cardiovascular disease protection in hypertension

- **ACE Inhibitors**
  The HOPE and EUROPA trials have suggested that ACE inhibitors may be cardioprotective in patients at high risk for cardiovascular disease, including patients with diabetes; the patients in these trials did not all have hypertension. In contrast, in the ALLHAT Hypertension Trial, the thiazide-like diuretic, chlorthalidone, was at least as effective as the ACE inhibitor lisinopril, in preventing cardiovascular complications in hypertensive patients with diabetes mellitus.

- **ARBS**
  ARBS have not yet been documented to be more cardioprotective than other drugs in hypertensive patients with diabetes mellitus. In the LIFE Trial they did provide superior cardiovascular protection to a beta-blocker-based regimen in patients with and without diabetes.

Renal disease protection in hypertension

- ACE inhibitors have specific renal protective effects in type 1 patients with diabetic nephopathy.
- ARBs have specific renal protective effects in type 2 patients with diabetic nephropathy.
- Both ACE inhibitors and ARBs slow progression from microalbuminuria to macroalbuminuria in type 2 patients with diabetes

Current recommendations:

- For patients with no albuminuria**,** the Joint National Committee on Prevention, Detection, Evaluation and Treatment of High Blood Pressure (JNC 7) recommends an ACE inhibitor, an ARB, or a thiazide diuretic for initial therapy in patients with hypertension and diabetes. The ADA recommends that all patients with diabetes and hypertension be treated with a regimen that includes an ACE inhibitor or an ARB.
- For patients with type 1 diabetes and any degree of albuminuria, the ADA recommends ACE inhibitors based on clinical trial support. For patients with type 2 diabetes and micro-albuminuria, either ACE inhibitors or ARBs are reasonable initial choices. ARBs should be strongly considered for type 2 diabetes patients with hypertension and macroalbuminuria (>300 mg/day).
- The efficacy of combining ACE inhibitors with ARBs – either for lowering blood pressure, reducing proteinuria, or preventing renal complications – has not yet been definitively demonstrated in clinical trials

Diuretics

Thiazide diurectics benefit patients with diabetes and hypertension, either as initial therapy in patients without albuminuria or as part of a combined regimen.
Thiazide diuretics are minimally effective in patients with estimated GFR below about 45 ml/1.73m^2, which correlates with a serum creatinine of about 1.8 mg/dL in men and 1.6 mg/dL in women. Loop diuretics may be necessary in these patients. Short-acting loop diuretics (furosemide, bumetanide) may need to be given bid-tid for hypertension control.

Beta-Blockers

Beta-blockers have demonstrated benefits in treating hypertension in persons with diabetes especially as part of a multi-drug regimen. However, beta-blockers may be less effective than ARBs for preventing cardiovascular complications in diabetes (LIFE Trial). Adding beta-blockers to ACE inhibitors may not reduce blood pressure as effectively as adding diuretics or calcium channel blockers to ACE inhibitors, especially in patients with heart rates below 84 beats/minute. Beta-lockers should be part of the treatment regimen for most patients with diabetes who are post-myocardial infarction or who have left ventricular dysfunction or angina. Their adverse metabolic effects – weight gain, elevation of blood glucose and triglycerides, and reduction of HDL cholesterol—are not absolute contraindications to their use.

Calcium Channel Blockers (CCBs)

Calcium channel blockers are useful components of combination therapy to reduce blood pressure in persons with diabetes. Long-acting dihydropyridine and non-dihydropyridine CCBs have both been shown to reduce cardiovascular complications in patients with diabetes as compared to placebo. CCBs prevent cardiovascular complications as effectively as ACE inhibitorsand diuretics in all categories except heart failure, where they are significantly inferior. Direct comparisons of dihydropyridine CCBs and non-dihydropyridine CCBs are not available with respect to cardiovascular or renal complications. However, non-dihydropyridine CCBs may be preferred in patients with diabetes and proteinuria, although dihydropyridine CCBs may also be safely used in these patients as long as there is concurrent therapy with an ACE inhibitor or ARB. Beta-blockers should generally be combined with dyhydropyridine CCBs rather than non-dihydropyridine CCBs, especially in elderly patients or patients with conduction abnormalities or baseline heart rates below 60 beats/minute. Combining the two classes of CCBs may effectively lower blood pressure in some patients with difficult to control hypertension.

Alpha-blockers

The ALLHAT study raises questions about potential adverse effects of the alpha-blocker doxazosin on incidence of cardiovascular outcomes. Until this has been further studied, alpha blockers should not be an initial choice for add-on therapy.

American Diabetes Association. Hypertension management in adults with diabetes. Diabetes Care 2004; (Suppl 1): S65-67

National High Blood Pressure Education Program Coordinating Committee. Seventh Report of the Joint National Committee on Prevention, Detection, Evaluation, and Treatment of High Blood Pressure. Hypertension 2003: 42:1206-1252

HYPERLIPIDEMIA

People with type 2 diabetes have an **increased prevalence of lipid abnormalities.** Therapy aimed at improving lipids has been shown to reduce macrovascular disease and mortality in these patients. Glycemic control can also beneficially lower plasma lipids, especially triglyceride levels (TG), and **probably reduce cardiovascular risk.**

Clinical trials have shown that diabetic patients with CHD benefit more than other CHD patients from lipid-lowering therapy. The American Diabetes Association has concluded that the primary emphasis should be placed on lowering LDL levels, but interventions to lower TG and raise HDL levels may also be useful. Data suggest treatment with statins may be appropriate for people >40 with total cholesterol ≥135 mg/dL.

Lipid Therapy Goals

Optimal LDL levels **<70-100 mg/dL**
In patients with vascular disease the LDL should be less than 70.

Optimal HDL levels **Men >40 mg/dL**
Women >50 mg/dL

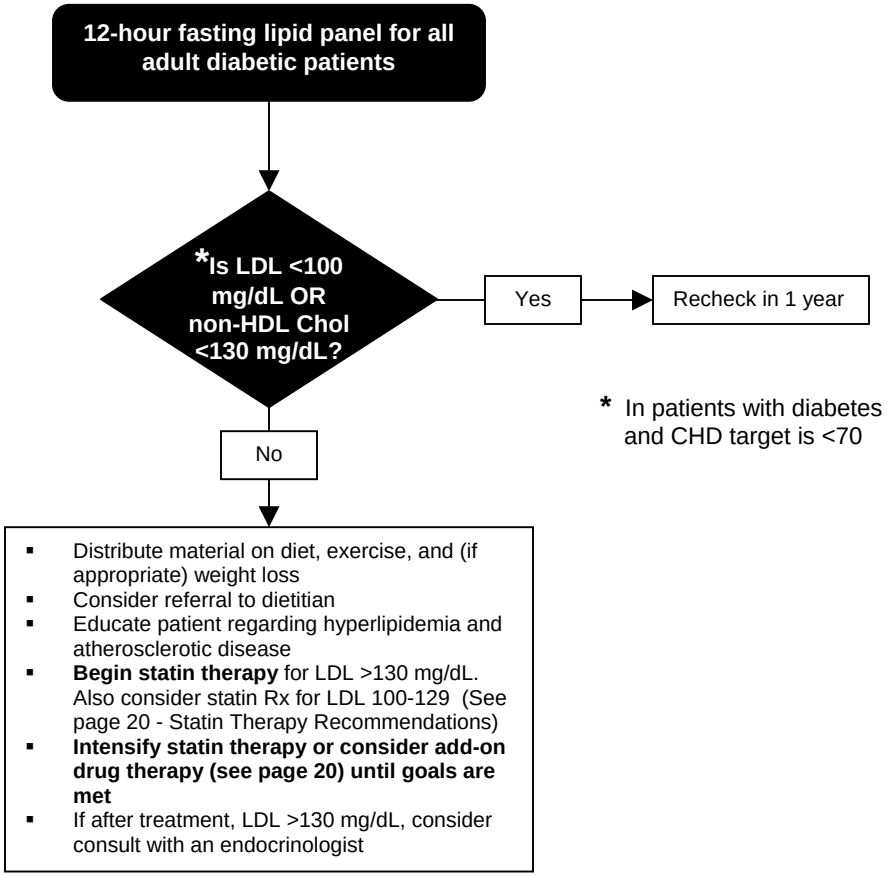
Desirable TG levels **<150 mg/dL**

Patients with TGs >1000 mg/dL demand immediate attention to get this level below 400 mg/dL.

Note: For patients with high triglycerides, some authorities have recently discussed an alternate goal for treatment as **non-HDL cholesterol <130 mg/dL.** Non-HDL cholesterol is defined as total cholesterol minus HDL cholesterol.

Algorithm

Pharmacological therapy is indicated if there is an inadequate response to lifestyle modifications and glycemic control. Statins are usually the drugs of choice.



STATIN THERAPY RECOMMENDATIONS

1. **Optimize statin therapy first, THEN add-on therapy options indicated in paragraph 2 below if needed**

2. **If patient is still unable to attain treatment goal with optimized statin therapy, consider the following options based on the patient's situation:**

   - **If LDL level remains above the individual's target,** consider add-on therapy with Zetia.[1]

   - **If TG remain >400 mg/dL,** a careful history of the patient's alcohol consumption should be obtained. Factors that may increase TG are listed to the right.

Factors that may increase triglycerides
Alcohol intake
Excessive carbohydrate intake
Poor glycemic control (improve HbA1c <7)
Oral estrogen therapy (discontinue estrogen or convert to transdermal estrogen)
Most beta blockers (discontinue beta blocker or convert to carvedilol)

   - **If TG remain >400 mg/dL,** and/or HDL <40 mg/dL (even in the rare patient with LDL <100 mg/dL), despite maximized statin, obtain good glycemic control and consider add-on therapy with a fibric acid derivative or niacin.[2] This combination is not well studied. It **requires patient consent and careful monitoring** and is associated with an increased risk for myositis or rhabdomyolysis.

   - **If goals remain unmet,** consider referral to an endocrinologist or lipid specialist.

Notes:

[1] Zetia should be used in conjunction with a statin only when lipid goals cannot be met with a statin alone. Zetia should NOT be used as a single agent unless the patient cannot tolerate a statin. There are no outcome data for the use of Zetia.

[2] If niacin is used, it should be done so with caution in patients with peptic ulcer disease or gout. Use of niacin in most patients does not cause a significant deterioration of glucose control but occasionally patients may experience worsening of glucose control.

NEUROPATHY

Foot problems, including acquired structural deformation, ulceration, and wound-healing failure, are frequent causes of morbidity and mortality in people with diabetes. Ulceration and wound-healing failure are frequent causes for lower extremity amputation. Once the amputation of one limb has occurred, the prognosis for the contralateral limb is poor.

Loss of sensation (neuropathy) may be the first sign leading to acquired deformity and/or amputation. Patients who can feel a monofilament line applied with 10 grams of pressure on selected sites most likely will not develop foot ulcers or acquired deformities. **Thus, the emphasis should be on identifying diabetic patients with high-risk feet, specifically feet with loss of protective sensation or with significant vascular disease.**

The foot evaluation should include careful questioning about claudication, evaluation of pulses, inspection of the feet, and a monofilament fiber examination. Consider a non-invasive vascular exam for patients without palpable pulses.

All identified high-risk patients should undergo a comprehensive program of patient education, including instruction on daily self-care and guidelines on appropriate footwear. Sometimes prescription footwear is helpful. Medicare will provide yearly reimbursement for the following items for diabetic patients with high-risk feet:

- One pair of extra-depth shoes and three pairs of inserts, or
- One custom-molded shoe plus two additional pairs of inserts

Diabetic foot ulcers require extensive evaluation. The evaluation should include the following:

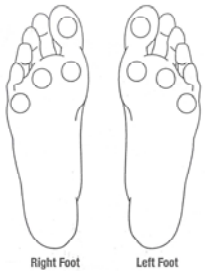
- Assessment of the surrounding tissue for signs of edema, cellulitis, and/or abscess.
- Evaluation for exudate, necrosis, and sinus tracts (The ability to gently probe through an ulcer to bone has been shown to be highly predictive of osteomyelitis)
- Evaluation of circulation to involved extremity

Diabetic foot ulcers are often polymicrobial: the primary cause is pressure. The goal for treatment must be removal of the pressure from the involved area. Early specialty consultation is encouraged.

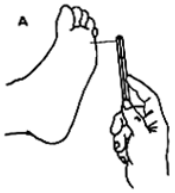
Monofilament Application Instructions

The sensory testing device used with the diabetic foot exam is a nylon filament mounted on a holder that has been standardized to deliver a 10-gram force when properly applied.

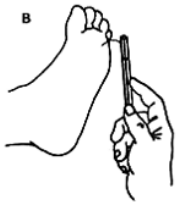
The sites to be tested are indicated below:



1. Apply the monofilament perpendicular to the skin's surface as shown below. The approach, skin contact, and departure of the filament should be approximately 1 ½ seconds in duration. Each site should be tested at least twice and use of sham testing is recommended. Apply the filament along the perimeter of, NOT on, an ulcer site, callus, scar, or necrotic tissue.



2. Apply sufficient force to cause the filament to bow into a C-shape as show below. Do not allow the filament to slide across the skin or to make repetitive contact at the test site.



3. Randomize the selection of test sites and time between successive tests to reduce the potential for patient guessing.
4. Ask the patient to respond "yes" when the filament is felt. Record the response

Monofilaments available through:

Lower Extremity Amputation Prevention Program
1-888-275—4772 (Press 1- HRSA information)
One time 50 monofilament order at no charge

Medical Monofilament Manufacturing
(508) 746-7877 (Disposable unit @ $0.30 each)

Reusable units @ $10 each can be ordered by calling: (800) 543-9055; or (225) 923-1297

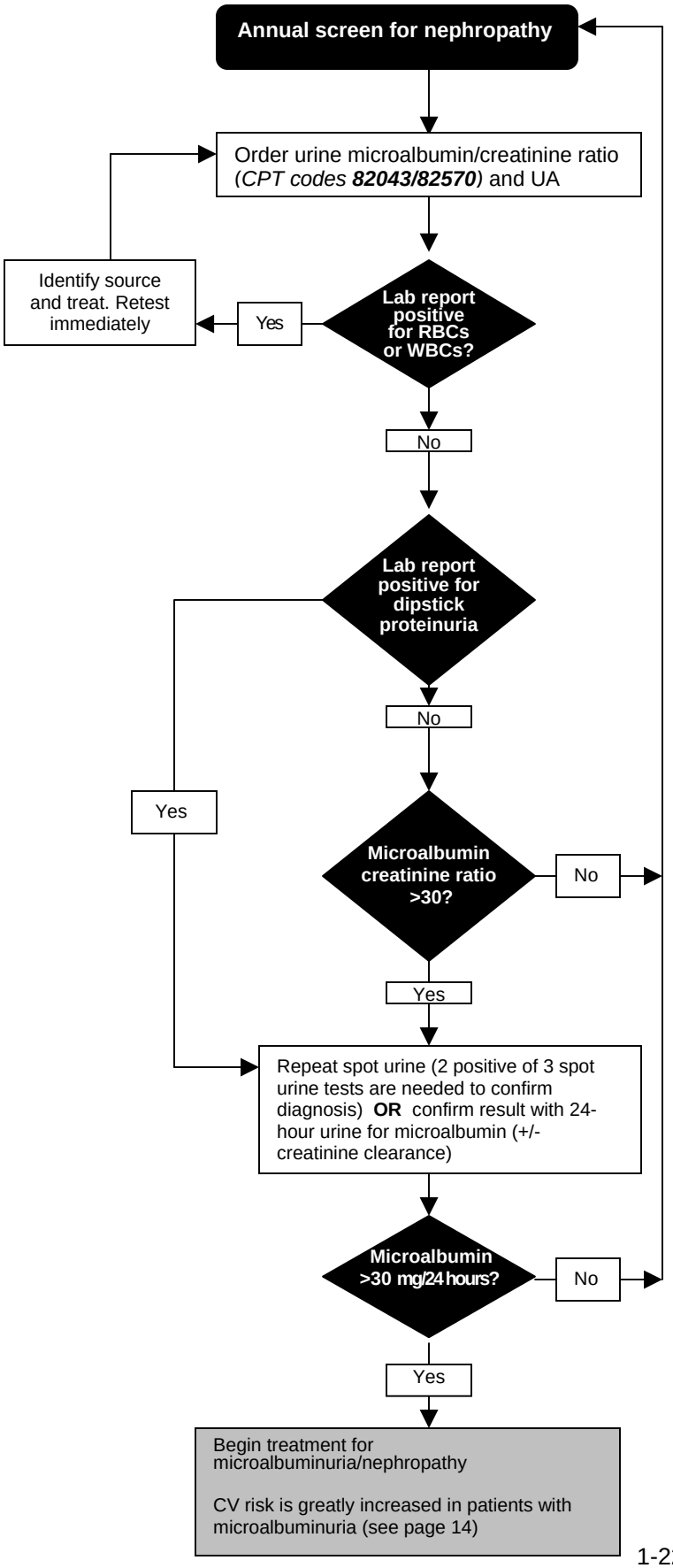
NEPHROPATHY

The onset of diabetic kidney disease can be detected at the earliest stage by testing for increased albumin excretion in the urine.

Normal: <30 mg/24 hours or <30 mg/gram of creatinine

The risk of progression of early diabetic kidney disease can be markedly reduced by the following:

- Maintenance of good glucose control (HbA1c <7.0%)
- Use of ACE inhibitors or ARBs even in normotensive subjects
- Blood pressure control ≤130/80 (Some experts suggest <125/75 for patients with nephropathy)
- Dietary protein restriction (0.8 g/kg/day initially and 0.6 g/k/day if creatinine clearance starts to fall)



RETINOPATHY AND DIABETIC EYE DISEASE

Diabetes is the leading cause of blindness in the United States for adults 20-74. Many of the early signs of diabetic retinopathy (notable on a dilated fundus examination) are asymptomatic for the patient. Early treatment can be the key to prevention of blindness.

The American Diabetes Association recommends an initial, and thereafter an annual, dilated and comprehensive eye exam by an ophthalmologist or optometrist who is knowledgeable and experienced in the diagnosis and management of diabetic retinopathy. Less frequent exams (2-year intervals) may be considered with the advice of an eye care professional for individual patients in good control and a normal exam. Patients with diagnosed diabetic retinopathy and patients with diabetes with prior normal eye exams who are, or become, pregnant should be referred promptly to an ophthalmologist.

Recommended Eye Examination Schedule for Type 1 and Type 2 Diabetes

Type of Patient	Minimum Routine Follow-up
Type 1 patients should have a dilated eye exam by an optometrist or ophthalmologist three to five years after diagnosis (Some evidence suggests that microvascular complications may develop before age 10 among those diagnosed as infants and toddlers) **Type 2** patients should have a dilated eye exam immediately following diagnosis for diabetes or pre-diabetes	**Annually for most patients** with mild or no non-proliferative diabetic retinopathy (NPDR) or microaneurysms **Biennially for patients in good control**, prior normal exam and with advice of an eye care professional **More frequent examination** is required with moderate or progressive mild NPDR
Pregnancy: women should have a dilated eye exam when planning pregnancy if possible, and also during the first trimester (Does not apply to women with gestational diabetes since they are not at increased risk for diabetic retinopathy)	**First trimester,** with continued close follow-up. Diabetic patients who become pregnant may experience accelerated diabetic retinopathy and should be monitored closely by an ophthalmologist
Patients with any macular edema, severe non-proliferative diabetic retinopathy (NPDR) or any proliferative diabetic retinopathy (PDR)	**Refer promptly** to an ophthalmologist experienced in the treatment of diabetic retinopathy*
Patients with vision loss from diabetes should be encouraged to pursue visual rehabilitation	**Refer** to an ophthalmologist or an optometrist who is trained or experienced in low-vision care

* Do not delay referral to an ophthalmologist until PDR develops. Early referral is very important for patients with type 2 diabetes and severe NPDR, since laser treatment at this stage is associated with a 50% reduction in risk of severe visual loss and vitrectomy.

Source: ADA Clinical Practice Recommendations, 2004. *Diabetes Care* 27 (Suppl. 1): S86

APPROVED DIABETES EDUCATION PROGRAMS

Diabetes self-management training (DSMT) is generally conducted in a hospital or clinic with group and individual instruction. DSMT consists of education from a 'team' of individuals from various disciplines. The 'team' may include nurses, dietitians, doctors, pharmacists, exercise physiologists, health educators, counselors and other knowledgeable health care professionals**.** An *individualized* program is based on an initial assessment, and may cover any or all of these topics depending on the needs of the patient:

- The diabetes disease process and treatment options
- Incorporating physical activity into a lifestyle
- Monitoring blood glucose, urine ketones (when appropriate), and using results to improve control
- Preventing, detecting and treating acute complications
- Goal setting to promote health, and solve problems of daily living
- Incorporating appropriate nutritional management
- Utilizing medications for therapeutic effectiveness
- Integrating psychosocial adjustment to daily life
- Promoting preconception care, management of pregnancy, and gestational diabetes
- Preventing (through risk reduction behavior), detecting, and treating chronic complications

For reimbursement, most health insurance plans require DSMT programs to meet the criteria set by the Utah Diabetes Prevention and Control Program (DPCP) or American Diabetes Association (ADA). Check with health plans to assure eligibility for reimbursement; some providers have approval pending.

Note: MEDICARE REIMBURSES ONLY FOR DSMT PROVIDED IN ADA APPROVED PROGRAMS.

Northern Utah - Box Elder, Cache, Davis, and Weber Counties

Brigham City Hospital		
Brigham City, Utah 84302	435-734-4339	ADA
Bear River Valley Hospital		
Tremonton, Utah 84337	435-257-7441	ADA
Budge Clinic		
Logan, Utah 84341	435-792-1707	ADA
Logan Regional Hospital		
Logan, Utah 84341	435-716-5439	ADA
Bountiful Health Center (IHC)		
Bountiful, Utah 84010	801-294-1000	ADA
Davis Hospital/ Medical Center (*ADA approval pending*)		
Layton, Utah 84041	800-423-0871	
Lakeview Hospital		
Bountiful, Utah 84010	801-299-2470	ADA
Endocrine and Diabetes Clinic (McKay-Dee)		
Ogden, Utah 84403	801-387-7919	ADA
McKay Dee Outpatient Diabetes Education		
Ogden, Utah 84403	801-387-7539	ADA

Salt Lake County

Alta View Hospital		
Sandy, Utah 84070	801-314-2894	ADA
Bryner Clinic		
Salt Lake City, Utah 84102	801-519-7192	ADA
Cottonwood Hospital		
Murray, Utah 84106	801-314-2894	ADA
Cottonwood Family Practice		
Salt Lake City, Utah 84121	801-262-3443	ADA
Cottonwood Internal Medicine		
Murray, Utah 84107	801-314-4300	ADA
Diabetes Specialty Center		
Salt Lake City, Utah 84115	801-268-9699	DPCP
Holladay Health Clinic (IHC)		
Salt Lake City, Utah 84124	801-314-2894	ADA
Jordan Valley Hospital		
West Jordan, Utah 84088	800-423-0871	ADA
LDS Hospital		
Salt Lake City, Utah 84143	801-314-2894	ADA
Medical Tower Family Practice		
Murray, Utah 84107	801-314-4266	ADA
Medical Tower Specialty Clinic		
Murray, Utah 8407	801-314-4890	ADA
Memorial Medical Center		
Salt Lake City, Utah 84105	801-461-7979	ADA
Pioneer Valley Hospital (*ADA approval pending*)		
West Valley City, Utah 84120	800-423-0871	
Sandy Health Center (IHC)		
Salt Lake City, Utah 84094	801-501-2100	ADA
St. Marks Hospital		
Salt Lake City, Utah 84124	801-268-7358	ADA
Salt Lake Clinic		
Salt Lake City, Utah 84102	801-535-8117	ADA
Salt Lake Regional Hospital (*ADA approval pending*)		
Salt Lake City, Utah 84102	800-423-0871	
Taylorsville Health Center (IHC)		
Taylorsville, Utah 84118	801-840-2100	ADA
Utah Diabetes Center, University of Utah		
Salt Lake City, Utah 84108	801-585-5413	ADA
West Jordan Health Center (IHC)		
West Jordan, Utah 84088	801-256-6343	ADA

APPROVED DIABETES EDUCATION PROGRAMS (continued)

Utah and Wasatch Counties

American Fork Hospital American Fork Utah, 84004 801-763-3471 ADA **Mountain View Hospital** Payson, Utah 84651 801-465-7045 ADA	**Utah Valley Regional Medical Center** Provo, Utah 84605 801-357-7546 ADA **Heber Valley Medical Center** Heber City, Utah 84032 435-654-2500 ADA

Central and Southwestern Utah

Central Valley Medical Center Nephi, Utah 84648 435-623-6092 ADA **Gunnison Valley Hospital** Gunnison, Utah 84634 435-528-3955 DPCP **Sevier Valley Hospital** Richfield, Utah 84701 435-893-0371 DPCP	**Garfield Memorial Hospital** Panguitch, Utah 84759 435-676-8811 DPCP **Dixie Regional Medical Center** St. George, Utah 84770 435-688-5085 ADA **Valley View Medical Center** Cedar City, Utah 84720 435-868-5000 ADA

Uintah Basin and Southeastern Utah

Allen Memorial Hospital Moab, Utah 84532 435-259-7191 DPCP **Castleview Hospital** Price, Utah 84501 435-636-4822 DPCP **Ashley Valley Medical Center** Vernal, Utah 84078 435-789-3342 X 174 ADA **Uintah Basin Medical Center** Roosevelt, Utah 84066 435-722-6121 X 363 ADA	**Blanding Family Practice** Blanding Utah 84511 435-678-3601 DPCP **Montezuma Creek Clinic** Montezuma Creek, Utah 84534 435-651-3291 DPCP **Monument Valley Health Center** Monument Valley, Utah 84536 435-727-3242 DPCP **Navajo Mountain Clinic** (Via Kayenta AZ 86033) Navajo Mountain, Utah 928-697-3067 DPCP

Additional Diabetes Self-Management Training Programs

In addition to the DSMT programs locations listed above, some providers of this service have not yet been formally approved. These programs generally fit into one of the following categories:

- Satellite locations of certified programs using the same instructors and curricula
- Providers who have not yet applied for State or ADA approval
- Providers who have not been able to comply with all formal requirements due to staffing shortages
- Programs that have contractual arrangements with third party payers and are able to secure reimbursement without certification

Since some health insurance plans will not reimburse for DSMT, patients should verify coverage when planning to receive services through any DSMT provider; however, the programs listed below may be more likely to experience reimbursement difficulties than those listed above because they lack formal approval.

Diabetes Specialty Center at Granger Clinic West Valley City, Utah 84120 801-965-3639 **Dixie Regional Medical Center at River Road Clinic** St. George, Utah 84770 435-688-6200	**Primary Children's at Utah Diabetes Center** Salt Lake City, Utah 84113 801-581-7761 **Mountain West Medical Center - Diabetes Education** Tooele, Utah 84074 801- 882-4163

In addition to the education programs listed here, all Utah Community Health Centers not listed above participate in a National Diabetes Collaborative and have training in diabetes treatment and education. If they have not been formally approved, the experience and training for diabetes educational services in those not listed is subject to fluctuations depending on staff availability and experience. Please call to ascertain the availability of self-management training in advance of referral.

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Contents Section 2—Diabetes in Pregnancy

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Endorsements

The following professional associations and groups have reviewed the Diabetes In Pregnancy section of the Utah Diabetes Practice Recommendations that apply to their respective clinical areas of interest. They have indorsed these Recommendations, to the extent they apply to their clinical areas, and found them to be consistent with applicable standards of care for women with diabetes in pregnancy. In extending their endorsement, it is recognized that these Recommendations, while outlining a general course of action for the majority of patients, do not substitute for informed clinical judgment on the exact course of treatment for individual patients.

American College of Physicians, Utah Chapter

American College of Obstetics and Gynecology, Utah Chapter

American College of Nurse Midwives, Region 5, Chapter 5 (pending)

Association of Diabetes Educators in Utah

Utah Academy of Family Practice

Utah Dietetic Association

Utah Ophthalmology Society

Utah Pharmacists Association

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GESTATIONAL DIABETES

Introduction

Gestational diabetes (GDM) is one of the more common challenges that can complicate obstetrical care. It is anticipated that the rate of GDM will continue to rise in proportion to the rate of type 2 diabetes wihin the population since they share common risk factors. In Utah, the rate of GDM has risen steadily over the past decade and currently affects 2.3% of all pregnancies (Utah Department of Health Report). Women with GDM are more likely to develop hypertensive disorders during pregnancy and have a several-fold higher risk of developing type 2 diabetes later in life. Offspring of women with GDM are more likely to be macrosomic, have obstetrical complications, develop hyperbilirubinemia, and have increased risk for type 2 diabetes later in life. Appropriate management of GDM may reduce the obstetrical risks for both the mother and baby.

Screening for Gestational Diabetes

Universal screening during pregnancy is controversial, and some organizations have recommended that only high-risk women with traditional risk factors for type 2 diabetes be screened. However, the vast majority of obstetrical groups employ universal screening, and if risk-stratification screening is employed, only 3% of women with GDM will remain undiagnosed yet only 10% of pregnant women will be exempted from screening. Given the increasing prevalence of both diabetes and GDM within the Utah population, the Diabetes In Pregnancy committee recommends that all pregnant women be screened for GDM unless it is clearly not warranted based upon the practitioner's clinical judgment.

Low-risk women must meet all of the following criteria:

1. Age <25 years
2. Not a member of a high-risk ethnic population
3. Pre-conception BMI <25 kg/m^2
4. No prior history of abnormal glucose tolerance
5. No prior history of obstetrical complications associated with GDM
6. No family history of diabetes in a first degree relative

Screening Test

Between 24 and 28 weeks of gestation, women should receive a 50 gram, 1 hour oral glucose challenge using a glucose solution (not jelly beans or other forms of glucose). This test may be performed without regard to prandial state. Due to the inherent imprecision of capillary glucose testing, glucose should be measured in the laboratory using venous blood. Using a threshold of $\geq$130 mg/dL for further diagnostic testing increases the sensitivity to nearly 100%, compared to about 80% using a threshold of $\geq$140 mg/dL. (See algorithm on page 2-5)

Diagnostic Criteria for Gestational Diabetes

If the screening test is abnormal (i.e. $\geq$ 130 mg/dL), a three-hour, 100 gram glucose tolerance test should be performed. This test should be administered in the morning after an 8-14 hour fast. The patient should not smoke before or during the test and should remain seated for the duration of the test. Prior to testing, the patient should be encouraged to follow an unrestricted carbohydrate diet (>150 grams of carbohydrate per day for 3 days) in order to avoid a false positive test. The diagnostic criteria for GDM are shown in the adjacent table, and in order to increase the sensitivity of this diagnostic procedure, the committee recommends that only one abnormal value is needed to confirm the diagnosis of GDM. In contrast, the American Diabetes Association (ADA) and the American College of Obstetricians and Gynecologists (ACOG) have stipulated that a positive test for a GDM diagnosis requires two or more thresholds to be exceeded in order to maintain the diagnostic specificity of this procedure. Some studies have found that 30% of those with just one abnormal value exceeded at least two thresholds when retested four weeks later. Because women with only one abnormal value have been shown to have an increased risk for a macrosomic infant, and because they are likely to be easily managed with simple dietary therapy, the recommended criterion of only one abnormal value would not seem burdensome to the health care system or patients and should enhance obstetrical outcomes.

Diagnostic Criteria for GDM*

Fasting	95 mg/dL
1 hour	180 mg/dL
2 hour	155 mg/dL
3 hour	140 mg/dL

*One value exceeding any of these thresholds is diagnostic for GDM

Treatment of Gestational Diabetes

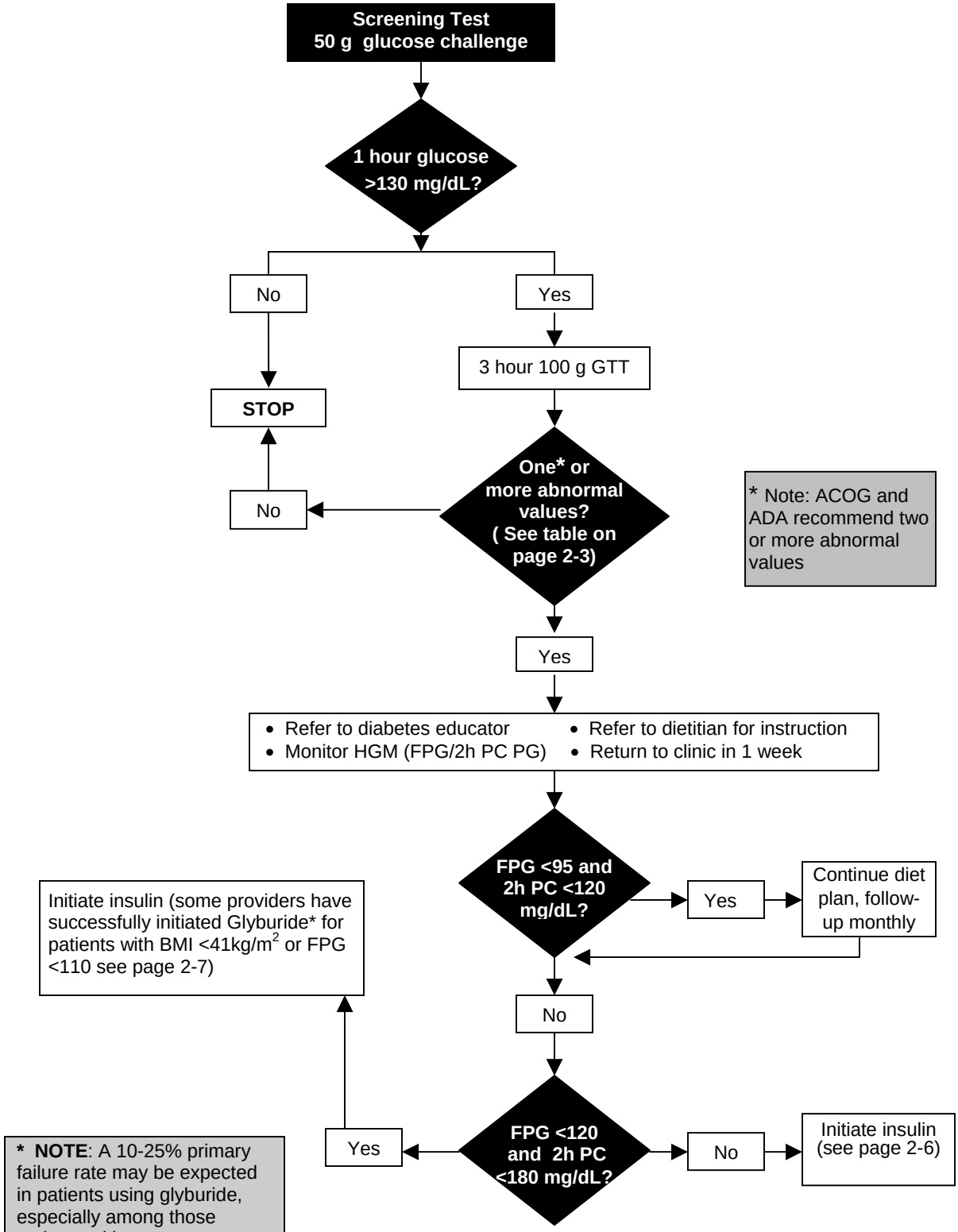
The management of GDM is summarized in the algorithms on the following pages. Several points concerning these algorithms must be emphasized:

- None of these medications is FDA approved (category A) for use in pregnancy
- The use of insulin glargine (Lantus®) and glyburide in pregnancy is clearly off label, and due to the lack of long-term information on safety, informed patient consent is recommended prior to initiating therapy with either agent, (see pages 2-11, and 2-12, for suggested patient consent forms)
- There are adequate data documenting the lack of transplacental transfer of glyburide (in contrast to other sulfonylureas). Other sulfonylureas are not recommended
- Glyburide should not be used prior to 11 weeks gestation,
- A 10-25% primary failure rate may be expected in patients using glyburide, particularly among those patients with pre-treatment high fasting plasma glucose rates (>110 mg/dL) and among obese patients with a body mass index (BMI) above 41 kg/m^2
- It is not recommended that Metformin (Glucophage®) be initiated during pregnancy given the lack of knowledge regarding its long term effects; however, some experts recommend that if metformin were used prior to pregnancy in a woman with polycystic ovary syndrome (PCOS), it may be continued during pregnancy in order to lessen the risk of developing GDM

Postpartum Evaluation

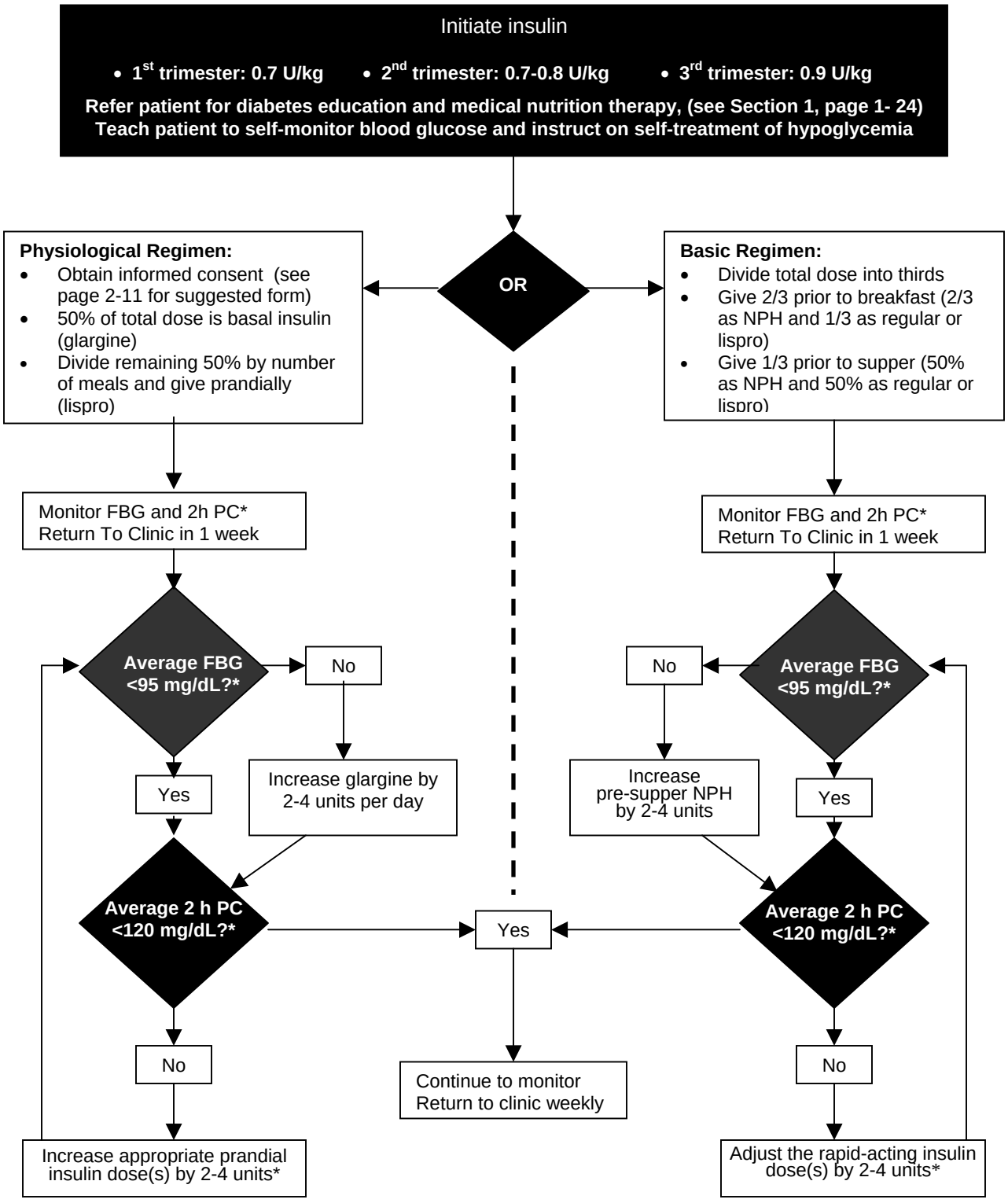
Approximately 15% of women with GDM will continue to experience glucose intolerance or exhibit overt diabetes in the non-pregnant state. The American Diabetes Association recommends screening with a fasting plasma glucose (FPG) 6-8 weeks after delivery with administration of a 75g GTT if further evaluation is indicated. Women who are diagnosed with GDM early in pregnancy, who are obese, and those who required insulin or glyburide therapy are more likely to experience continued glucose intolerance or diabetes. It is unlikely that patients who have remained normal during the first 6 weeks postpartum will have an abnormal GTT. However, even for patients who return to a normal glycemic state, evaluation at least every 3-years is recommended. If the patient continues to have glucose intolerance or impaired fasting glucose without diabetes, she should receive intensive medical nutrition therapy (MNT) and be placed on an individualized exercise program. All patients who have had GDM should be encouraged to exercise and lose weight if they are overweight to reduce their very high risk of developing type 2 diabetes, and should be followed up at least annually. Before the next pregnancy they should be re-evaluated and treated if necessary to decrease the risk of major fetal malformations.

GESTATIONAL DIABETES SCREENING AND INITIAL MANAGEMENT PROTOCOL



INSULIN ALGORITHM FOR GESTATIONAL DIABETES

(Inclusion of glargine in this algorithm does not imply endorsement by the committee)

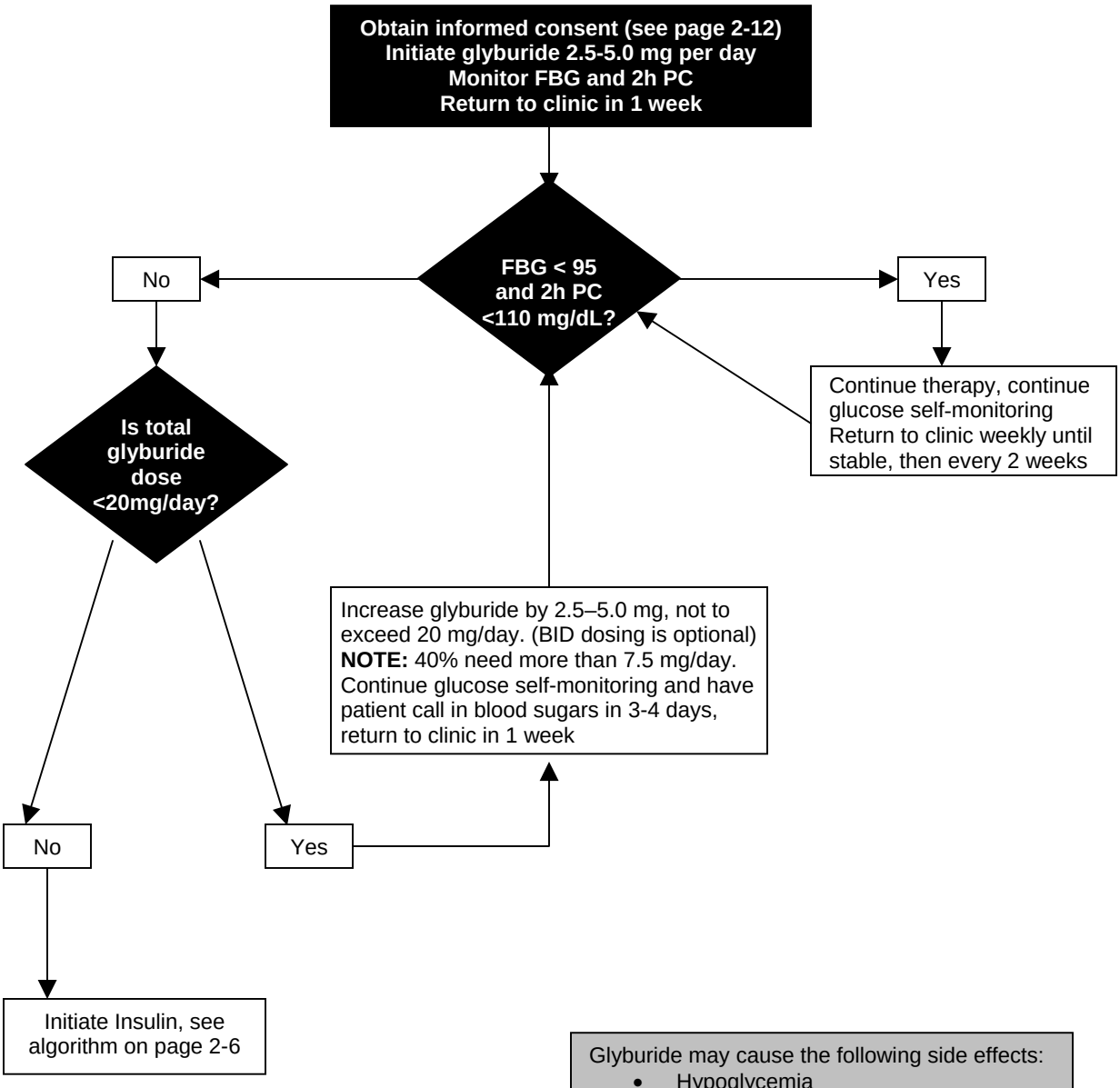


*With recurring hypoglycemia, reduce the dose of the corresponding insulin by 2-4 units

GLYBURIDE ALGORITHM FOR GESTATIONAL DIABETES

(Inclusion of this algorithm does not imply endorsement by the committee)

NOTE: Glyburide has been used by some practitioners for pre-selected patients with FPG <110 mg/dL and BMI <41kg/m^2. Current glyburide therapy data are from limited studies. Other sulfonylureas are not recommended.



Glyburide may cause the following side effects:

- Hypoglycemia
- Malaise
- Nausea
- Light headedness

PRE-EXISTING TYPE 1 AND TYPE 2 DIABETES

Preconception Counseling

Malformations fatal to the fetus and malformations involving multiple organ systems occur in 6-12% of infants born to mothers with diabetes, a rate six times higher than infants born to non-diabetic mothers. The first 5-8 weeks after the last menstrual period is the critical period of organogenesis during which poor glycemic control can have devastating effects. The A1C level is closely correlated with the risk of anomalies. Some studies have shown that an A1C of 8.5% or less is related to a malformation rate of 3.4%, while an A1C over 9.5% resulted
in a rate of nearly 22%. Increased rates of spontaneous abortion have also been linked to poor preconception control. Women with an A1C >7% who are planning pregnancy, should be referred for diabetes education from a certified or recognized diabetes self-management education program (see pages 1-24, 25 in *Section 1-Diabetes Management for Adults*)

Both spontaneous abortion and major fetal anomalies can be reduced through good preconception and postconception control. Unfortunately, less than one third of women with diabetes receive preconception counseling. Thus, it becomes imperative that health care providers use every visit as an opportunity to counsel female patients about pregnancy risks.

Preconception counseling should focus on achieving optimal glucose control, as low as possible without undue hypoglycemia, but no more than 7%, and promoting a healthy lifestyle before conception. **ACE-inhibitors should be discontinued and patients on oral hypoglycemic agents should be switched to insulin**. Evaluation for vasculopathy is recommended. It is essential that family planning be emphasized, including the use of oral contraceptives, barrier methods, IUDs and sterilization as appropriate.

Retinopathy

Despite the fact that transition to tight glycemic control during pregnancy has been linked to transitory progression of retinopathy, the goal, nevertheless, is to maintain glucose levels as close to normal as possible. Retinopathy is also more likely to occur or progress in hypertensive patients. Active proliferative retinopathy can worsen in pregnancy and should ideally be controlled with laser therapy before conception. All patients should be referred for screening retinal exams at their first prenatal visit. Follow-up exams both during and after pregnancy are strongly encouraged if retinopathy is present. (See page 1-23)

Renal disease

Nephropathy during pregnancy is estimated at 5-10%. Pregnancies complicated by nephropathy are at increased risk for maternal and fetal morbidity and perinatal mortality. With nephropathy, the risk of maternal hypertensive complications, including preeclampsia, preterm birth and fetal growth restriction is heightened. Decreased creatinine clearance and proteinuria measures of renal dysfunction are the primary predictors of
poor perinatal outcome. The following tests are recommended: 24-hr urine for protein; creatinine clearance; plus full renal function tests - serum electrolytes, BUN, creatinine. Women with incipient renal failure (i.e. serum creatinine >3 mg/dL or creatinine clearance <50 mL/min) should be counseled that pregnancy may induce a permanent deterioration of renal function in >40% of patients. In less severe cases of nephropathy, renal
function may deteriorate transiently during pregnancy. Patients with a history of microalbuminiuria or those with diabetes of ten or more years duration, should be screened with a 24-hour urine collection for total protein and creatinine before pregnancy or at the initial prenatal visit.

Coronary Artery Disease

The hemodynamic changes associated with pregnancy increase myocardial stress. At especially high risk are those patients with long-standing disease who have developed hypertension and nephropathy. It has been suggested that epinephrine released in response to hypoglycemia may exacerbate the risk for myocardial injury. Coronary artery disease is a relative contraindication to pregnancy. Women with this condition should undergo preconception counseling and be informed of the risks before attempting pregnancy. Referral for a cardiology consult is recommended and baseline studies, including an electrocardiogram and echocardiography should be considered.

Other Maternal Complications

Peripheral and autonomic diabetic neuropathy have not been well studied in pregnancy. Nausea and vomiting commonly seen during pregnancy might be exacerbated in patients with gastroparesis. Peripheral neuropathy should be assessed at the preconception visit or early in gestation by a careful examination of the patient's extremities for sensory loss (see page 1-21 in *Section 1 – Diabetes Management for Adults*). Instruction on foot care should be provided for all women with diabetes.

Diabetes Management During Pregnancy

During pregnancy, caloric requirements are increased. New guidelines advocate the use of carbohydrate counting as an option that may provide more flexibility during pregnancy.

- **Caloric intake should be managed for appropriate weight gain during pregnancy with special attention given to avoid excessive weight gain or any weight loss.**
- **For women of normal body weight, total caloric intake is usually 30 kcal/kg/day with an increase to 35 kcal/kg/day in women less than 90% of desirable body weight and 25 kcal/kg/day in those over 120% of desirable body weight.**
- **Meal planning with a registered dietitian is strongly recommended**

Insulin is the mainstay of therapy. Metformin has not been well studied in pregnancy and it has been recommended by some experts that the drug be stopped once pregnancy has been diagnosed; however, some experts recommend that if metformin was used prior to pregnancy in a woman with polycystic ovary syndrome (PCOS), it may be continued during pregnancy. Metformin should not be *initiated* during pregnancy. (Refer to page 2-4)

For women already using insulin, dose requirements may actually decrease in the first trimester. However, insulin requirements generally increase as the pregnancy progresses, particularly between 28-32 weeks. In the third trimester any dose decrease due to hypoglycemia should be reported immediately to a provider; this may represent a decrease in placental function. Maintaining glucose levels as close to normal as possible
is the goal of therapy. Urine or plasma ketones should be measured if glucose levels are repeatedly elevated (>200 mg/dL), and if positive, the results must be immediately reported to the provider. The values in the table below are targets for fasting and postprandial self-monitoring for both whole blood meters and plasma meters. The target for A1C is no higher than 6-7% or as low as possible without undue risk of hypoglycemia.

Achievement of glucose control depends on patient motivation, an understanding of the complex interactions between food, insulin, and exercise, as well as support from the health care team, including the obstetrician or perinatologist, registered dietitian, diabetes educator, and the patient's ability to recognize hypoglycemia

Maintaining glucose levels as close to normal as possible is the goal of therapy, including the following targets:

	Self-Monitored Whole Blood Glucose (mg/dL)	Self-Monitored Plasma Glucose (mg/dL)
Fasting/before meals	**≤ 95**	**≤105**
1 hour after meals	**≤140**	**≤155**
2 hours after meals	**≤120**	**≤130**

Rapid acting insulins are administered before meals to reduce postprandial glucose elevation associated with eating and allow utilization of consumed foods. Longer-acting insulins are basal insulins, used to restrain hepatic glucose production between meals and in the fasting state. Long-acting insulins, NPH (twice daily) or glargine (once daily) may be administered. The experience with glargine in pregnancy is limited and must be explained to the patient. It is strongly recommended that off-label use of diabetic medications be done with informed patient consent (see pages 2-11, 12).

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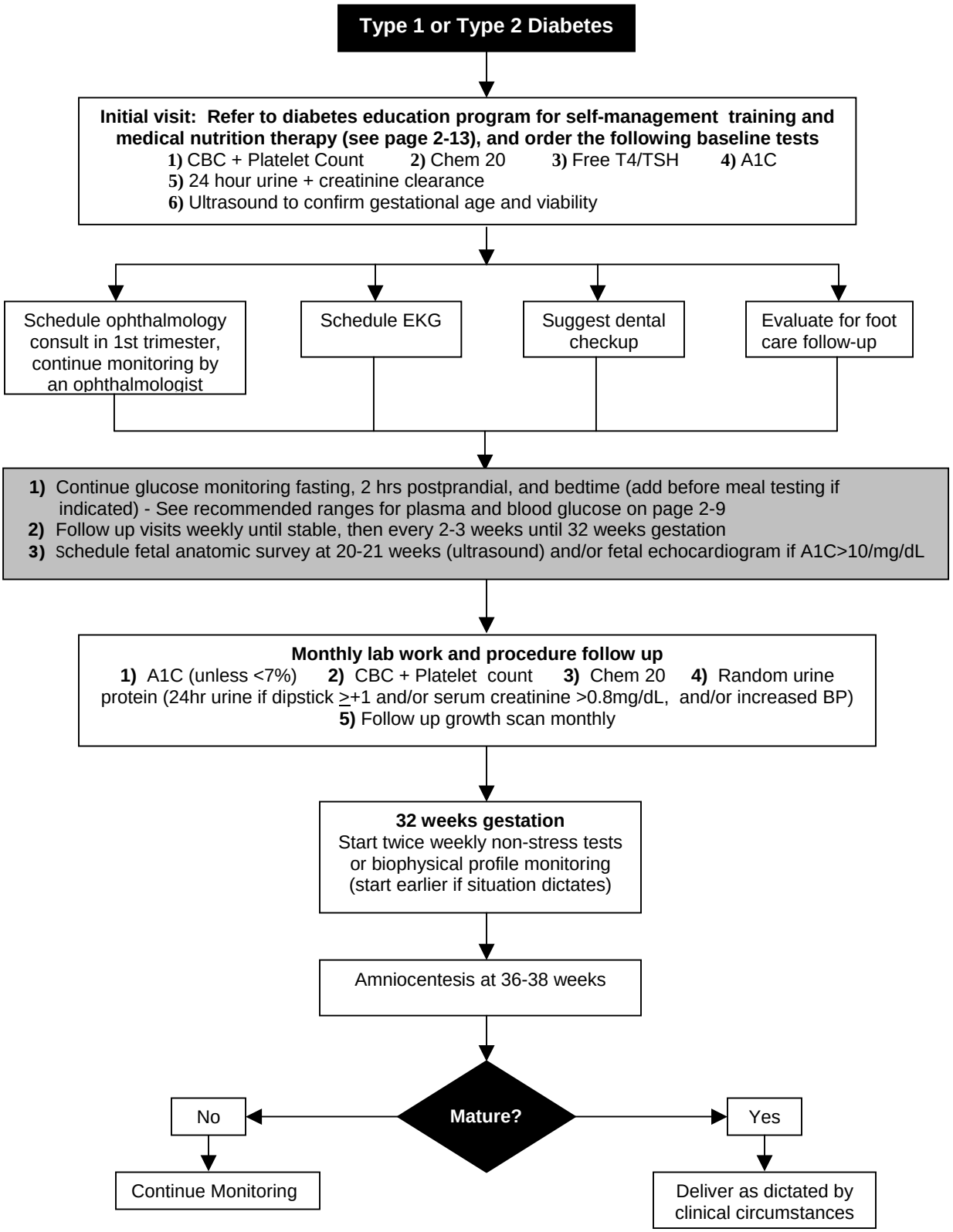
PREGNANCY WITH PRE-EXISTING DIABETES

MANAGEMENT AND MONITORING



LANTUS INFORMED CONSENT FORM

You are pregnant and are being treated for diabetes. It is very important to keep your blood sugar levels as normal as possible in order to prevent serious complications to both you and your unborn baby.

There are no FDA "approved" medicines to control blood glucose levels during pregnancy; however, the usual treatment is to use human insulin products. But over the past several years, newer man-made insulins have become available and are being safely used in women with diabetes who are pregnant.

Your doctor feels that you would benefit from using insulin glargine **Lantus®**. At the present time, there are no reports that show Lantus® causes problems with unborn babies. Because there have been only limited reports on the use of Lantus® there still may be a risk of substantial or serious harm. It is known that high blood sugars are a major risk to your baby. Your doctor believes that using Lantus® will reduce this risk.

– –

My questions about the use of Lantus® have been answered satisfactorily, and I, (print name) _____, understand and accept the risks of possible substantial and serious harm and agree to use Lantus® during pregnancy.

Patient Signature: _____ Date: _____

Witness Signature: _____ Date: _____

FORMA DE CONSENTIMIENTO PARA EL LANTUS

Usted está embarazada y recibe tratamiento para la diabetes. Es muy importante de mantener los niveles de azúcar en la sangre lo mas normal posible para prevenir complicaciones en usted y su bebé.

La FDA (Administración de drogas y alimentos de los Estados Unidos) no ha aprobado ningún medicamento para controlar el azúcar durante el embarazo, sin embargo el tratamiento usual consiste en inyectarse productos de insulina humana. Con el pasar de los años se han producido nuevas formas de insulina que son administradas sin problemas en mujeres embarazadas con diabetes.

Su médico opina que usted se beneficiaría usando glargine **(Lantus®).** Hasta el momento, no hay reportes que indican que Lantus® causa problemas con el bebé que usted esta esperando, pero debido a que se han realizado estudios limitados aun puede haber un riesgo sustancial o un daño serio. La alta cantidad de azúcar en la sangre constituye un gran riesgo para la salud de su bebé. Su médico cree que usando glargine (Lantus®) reduciría ese riesgo.

– –

Mi pregunta acerca del uso de (Lantus®) ha sido respondida satisfactoriamente, Yo, _____, entiendo y acepto el posible riesgo sustancial y el serio daño y estoy de acuerdo de usar Lantus® durante el embarazo.

Firma de la Paciente _____ Fecha: _____

Firma del Testigo_____Fecha:_____

GLYBURIDE INFORMED CONSENT FORM

You are pregnant and are being treated for diabetes. It is very important to keep your blood sugar levels as normal as possible in order to prevent serious complications to both you and your unborn baby.

There are no FDA "approved" medicines to control blood glucose levels during pregnancy; however, the usual treatment is to use human insulin products. But over the past several years, studies have shown that **glyburide** can be safely used in women with diabetes who are pregnant.

Your doctor feels that you would benefit from using glyburide. At the present time, there are no reports that show glyburide causes problems with unborn babies. Because there have been only limited studies there still may be a risk of substantial or serious harm. It is known that high blood sugars are a major risk to your baby. Your doctor believes that using glyburide will reduce this risk.

– –

My questions about the use of glyburide have been answered satisfactorily, and I, (print name) _____, understand and accept the risks of possible substantial and serious harm and agree to use glyburide during pregnancy.

Patient Signature: _____ Date: _____

Witness Signature: _____ Date: _____

FORMA DE CONSENTIMIENTO PARA EL GLYBURIDE

Usted está embarazada y recibe tratamiento para la diabetes. Es muy importante de mantener los niveles de azúcar en la sangre lo mas normal posible para prevenir complicaciones en usted y su bebé.

La FDA (Administración de drogas y alimentos de los Estados Unidos) no ha aprobado ningún medicamento para controlar el azúcar durante el embarazo, sin embargo el tratamiento usual consiste en inyectarse productos de insulina humana. Con el pasar de los años estudios han demostrado que **glyburide** puede ser seguro cuando es usado en mujeres embarazadas con diabetes.

Su médico opina que usted se beneficiaría usando glyburide. Hasta el momento, no hay reportes que indican que glyburide causa problemas con el bebé que usted está esperando, pero debido a que se han realizado estudios limitados aun puede haber un riesgo sustancial o un daño serio. La alta cantidad de azúcar en la sangre constituye un gran riesgo para la salud de su bebé. Su médico cree que usando glyburide reduciría ese riesgo.

– –

Mi pregunta acerca del uso de glyburide ha sido respondida satisfactoriamente, Yo, _____, entiendo y acepto el posible riesgo sustancial y el serio daño y estoy de acuerdo de usar glyburide durante el embarazo.

Firma de la Paciente _____ Fecha: _____

Firma del Testigo_____Fecha:_____

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